#### Humana.

#### 2025 Super National-5 MAPD

- Formulary ID 25459 Version 16
- Formulary ID 25456 Version 16
- Formulary ID 25458 Version 16

You can contact Humana for the most recent list of drugs by calling 1-800-457-4708 or, for TTY users, 711, five days a week April 1 - September 30 or seven days a week October 1 - March 31 from 8 a.m. - 8 p.m. Our automated phone system is available after hours, weekends, and holidays. Our website is also available 24 hours a day 7 days a week, by visiting Humana.com.

Prior Authorization Criteria Effective 08/01/2025

#### abiraterone - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prostate Cancer (metastatic castration-resistant): Members with severe hepatic impairment (Child-Pugh Class C). Prostate Cancer (metastatic castration-sensitive): Members with severe hepatic impairment (Child-Pugh Class C).
Required Medical Information	Prostate Cancer (metastatic castration-resistant): The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC). The member will be using abiraterone acetate in combination with prednisone. Prostate Cancer (castration-senstitive): The member has diagnosis of castration-sensitive prostate cancer plus one of the following scenarios: metastatic (stage IV) disease OR Node-positive (any T, N1) OR localized disease with high risk features that is persistent or recurrent after prior radical prostatectomy and/or radiation therapy. Member will be using abiraterone acetate in combination with prednisone and one of the following applies: in combination with LHRH analog (e.g, Lupron, Trelstar) OR has previous bilateral orchiectomy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### abiraterone - TABLET

Other Criteria	
Part B Prerequisite	0

## abirtega - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prostate Cancer (metastatic castration-resistant): Members with severe hepatic impairment (Child-Pugh Class C). Prostate Cancer (metastatic castration-sensitive): Members with severe hepatic impairment (Child- Pugh Class C).
Required Medical Information	Prostate Cancer (metastatic castration-resistant): The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC). The member will be using abiraterone acetate in combination with prednisone. Prostate Cancer (castration-senstitive): The member has diagnosis of castration-sensitive prostate cancer plus one of the following scenarios: metastatic (stage IV) disease OR Node-positive (any T, N1) OR localized disease with high risk features that is persistent or recurrent after prior radical prostatectomy and/or radiation therapy. Member will be using abiraterone acetate in combination with prednisone and one of the following applies: in combination with LHRH analog (e.g, Lupron, Trelstar) OR has previous bilateral orchiectomy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### acitretin - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member must have a diagnosis of severe cutaneous psoriasis including plaque, guttate, erythrodermic, palmar-plantar, and pustular types AND the member has had previous treatment, contraindication, or intolerance to methotrexate or cyclosporine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## ACTIMMUNE - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Granulomatous Disease (CGD): The member has chronic granulomatous disease (CGD). The member is using Actimmune to reduce the frequency and severity of infections. Severe Malignant Osteopetrosis: The member has severe malignant osteopetrosis. The member is using Actimmune to delay time to disease progression.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## acyclovir - OINTMENT (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must have a diagnosis of genital herpes OR member has a diagnosis of non-life-threatening mucocutaneous Herpes Simplex Virus (HSV) infection and is immunocompromised. The member has had previous treatment, contraindication, or intolerance with oral acyclovir and valacyclovir.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## ADALIMUMAB-ADAZ - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

### ADALIMUMAB-ADAZ - SYRINGE (ML)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

### ADALIMUMAB-ADBM - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

### ADALIMUMAB-ADBM - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

# ADALIMUMAB-ADBM(CF) PEN CROHNS - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## ADALIMUMAB-ADBM(CF) PEN CROHNS - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

### ADALIMUMAB-ADBM(CF) PEN PS-UV - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## ADALIMUMAB-ADBM(CF) PEN PS-UV - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## ADCETRIS - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	For Hodgkin lymphoma (relapsed or refractory), Hodgkin Lymphoma Post-auto-HSCT Consolidation, Large B-Cell Lymphoma (LBCL), Systemic Anaplastic Large Cell Lymphoma (sALCL) (relapsed or refractory), Primary Cutaneous Anaplastic Large Cell Lymphoma (pcALCL) or CD30-expressing Mycosis Fungoides (MF): Members that have experienced disease progression while on Adcetris.
Required Medical Information	Hodgkin lymphoma. Diagnosis of relapsed or refractory Hodgkin lymphoma. The member has documented evidence of progression following an autologous stem cell transplant OR is not a candidate for an autologous stem cell transplant but documented evidence of progression on at least two previous multi-agent chemotherapy regimens OR the member will be using Adcetris (brentuximab) as palliative therapy for older adults (age greater than 60). The member will be using Adcetris as monotherapy or in combination with bendamustine. Systemic Anaplastic Large Cell Lymphoma (sALCL) (relapsed or refactory). Diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma. The member has documented evidence of progression on at least one prior multi-agent chemotherapy regimen The member will be using Adcetris (brentuximab vedotin) as monotherapy. Disease has confirmed CD30 positivity. Hodgkin Lymphoma Post-auto-HSCT Consolidation: The member has a diagnosis of classical Hodgkin lymphoma AND The member will be using Adcetris (brentuximab vedotin) as post-autologous hematopoietic stem cell transplant (HSCT) consolidation AND The member is at high risk of post-autologous HSCT relapse or progression (must meet at least one of the following criteria): Refractory disease to front-line therapy, Relapsed disease with extranodal disease to front-line therapy. Previously untreated Hodgkin lymphoma. The member has a diagnosis of stage III or IV classical Hodgkin lymphoma AND The member has previously untreated disease AND The member will be using Adcetris (brentuximab vedotin) in combination with doxorubicin, vinblastine, and dacarbazine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## ADCETRIS - VIAL (EA)

Other Criteria	Primary Cutaneous Anaplastic Large Cell Lymphoma (pcALCL) or CD30 -expressing Mycosis Fungoides (MF). The member has a diagnosis of primary cutaneous anaplastic large cell lymphoma (pcALCL) or CD30- expressing mycosis fungoides (MF) AND The member has received at least one prior systemic therapy AND The member will be using Adcetris (brentuximab vedotin) as monotherapy. Large B-Cell Lymphoma (LBCL). The member has a diagnosis of relapsed or refractory LBCL, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) AND The member has received 2 or more lines of prior systemic therapy AND The member is ineligible for autologous hematopoietic stem cell transplantation or chimeric antigen receptor (CAR) T-cell therapy AND Adcetris (brentuximab vedotin) will be used in combination with lenalidomide and a rituximab product. Systemic Anaplastic Large Cell Lymphoma (SALCL) or other CD30-expressing Peripheral T-cell Lymphomas (PTCL). The member has a diagnosis of systemic anaplastic large cell lymphoma (sALCL) or peripheral T-cell lymphomas (PTCL) (e.g. angioimmunoblastic T-cell lymphoma and PTCL not otherwise specified) AND There is documented CD30-positivity (e.g. greater than 10% by immunohistochemistry) AND The member will be using in combination with cyclophosphamide, doxorubicin, and prednisone AND The request is for previously untreated disease.
Part B Prerequisite	0

#### **ADEMPAS - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Chronic Thromboembolic Pulmonary Hypertension (CTEPH). The member must have a diagnosis of Chronic Thromboembolic Pulmonary Hypertension (CTEPH) (WHO Group 4) AND The member must have CTEPH classified as inoperable or persistent/recurrent after surgical treatment (i.e. pulmonary endarterectomy). Pulmonary Arterial Hypertension (PAH). The member must have a diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

## ADSTILADRIN - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on Adstiladrin (nadofaragene firadenovec-vncg)
Required Medical Information	Non-muscle invasive bladder cancer (NMIBC): Member has a diagnosis of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive disease, which is defined as persistent or recurrent disease following adequat BCG therapy (adequate BGC is defined as the administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course) AND member has non-muscle invasive bladder cancer (NMIBC) with documented carcinoma in situ (CIS) AND member is ineligible for or has elected not to undergo cystectomy.
Age Restriction	Member is 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### ADVAIR DISKUS - BLISTER, WITH INHALATION DEVICE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member must have a previous treatment, intolerance or contraindication to an AB-rated generic equivalent product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### AKEEGA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following PARP inhibitor therapy [e.g., Rubraca (rucaparib), Lynparza (olaparib), Zejula (niraparib)].
Required Medical Information	Prostate Cancer: Member has a diagnosis metastatic castration-resistant prostate cancer (mCRPC) AND Member has documented deleterious or suspected deleterious BRCA-mutated (BRCAm) disease AND Member will use in combination with prednisone or prednisolone AND Member will use Akeega (niraparib and abiraterone acetate) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or concurrent GnRH analog).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **ALECENSA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Alecensa (alectinib). Non-Small Cell Lung Cancer (Adjuvant): The member exceeds two years of total Alecensa (alectinib) treatment.
Required Medical Information	Non-small Cell Lung Cancer: The member has recurrent or metastatic non-small cell lung cancer AND The member has documented anaplastic lymphoma kinase (ALK)-positive disease AND The member will be using Alecensa (alectinib) as monotherapy. Non-small Cell Lung Cancer (Ajuvant): The member has a diagnosis of non-small cell lung cancer (NSCLC) [i.e., tumors greater than or equal to 4 cm or node positive] AND The member will be using Alecensa (alectinib) for adjuvant treatment following complete tumor resection AND The member has documented anaplastic lymphoma kinase (ALK)-positive disease AND The member will be using Alecensa (alectinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

## ALIQOPA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following a PI3K inhibitor (e.g. idelalisib, copanlisib)
Required Medical Information	Follicular Lymphoma: The member has a diagnosis of follicular lymphoma AND The member has relapsed, refractory, or progressive disease AND The member has received at least two prior systemic therapies AND The member will be using Aliqopa as monotherapy
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA
Part B Prerequisite	0

#### alosetron - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of severe diarrhea-predominant irritable bowel syndrome, AND The member has chronic IBS symptoms (lasting 6 months or longer), AND The member has had previous treatment with, contraindication, or intolerance to at least two of the following: loperamide, a tricyclic antidepressant (e.g. amitriptyline, nortriptyline, imipramine HCI, desipramine), or Xifaxan.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### ALUNBRIG - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members experience disease progression on Alunbrig (brigatinib).
Required Medical Information	Non-Small cell lung cancer: The member has a diagnosis of advanced or metastatic NSCLC with documented anaplastic lymphoma kinase (ALK) positivity AND Alunbrig will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

### alyq - TABLET

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### ambrisentan - TABLET

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has a diagnosis of idiopathic pulmonary fibrosis.
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

## ANKTIVA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on Anktiva (nogapendekin alfa inbakicept-pmln).
Required Medical Information	Non-muscle invasive bladder cancer (NMIBC): Member has a diagnosis of non-muscle invasive bladder cancer (NMIBC) with documented carcinoma in situ (CIS) AND The disease is documented as Bacillus Calmette-Guerin (BCG)-unresponsive, which is defined as persistent or recurrent disease following adequate BCG therapy (Adequate BCG is defined as the administration of at least five of six doses of an initial induction course plus either of: at least two of three doses of maintenance therapy or at least two of six doses of a second induction course) AND Member is ineligible for or has elected not to undergo cystectomy AND Anktiva (nogapendekin alfa inbakicept-pmln) will be used concurrently with Bacillus Calmette-Guerin (BCG).
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	
Part B Prerequisite	0

#### **APTIOM - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: Member has a diagnosis of partial-onset (focal) seizures AND Member will not use Aptiom (eslicarbazepine) in combination with oxcarbazepine AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## ARCALYST - VIAL (EA)

	1
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Familial Cold Autoinflammatory Syndrome or Muckle-Wells Syndrome: The member has a diagnosis of Cryopryin-Associated Periodic Syndrome (CAPS), including Familial Cold Autoinflammatory Syndrome (FCAS) and Muckle-Wells Syndrome (MWS). Recurrent Pericarditis: Member has a diagnosis of recurrent pericarditis defined by: presentation of symptoms of acute pericarditis after a symptom-free interval of at least 4 weeks. Deficiency of Interleukin-1 Receptor Antagonist (DIRA) The member has a diagnosis of deficiency of interleukin-1 receptor antagonist (DIRA).
Age Restriction	Member must be 12 years of age or older for Familial Cold Autoinflammatory Syndrome, Muckle-Wells Syndrome, and Recurrent Pericarditis indications. Age restriction does not apply to DIRA.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### ARIKAYCE - VIAL, NEBULIZER (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use of Arikayce as monotherapy. Use of Arikayce for non-MAC infections or for non-refractory or disseminated MAC. Continued use of Arikayce in members that failed to achieve negative sputum cultures after 6 months of therapy with Arikayce.
Required Medical Information	Mycobacterium avium Complex (MAC) Lung Disease. Member must have a diagnosis of Mycobacterium avium complex (MAC) lung disease. Member must have failed to achieve negative sputum cultures after a minimum of 6 consecutive months of a multi-drug regimen. Member must have limited or no alternative treatment options. Arikayce will be used as part of a multi-drug regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## arsenic trioxide - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute Promyelocytic Leukemia (APL). The member has a diagnosis of acute promyelocytic leukemia AND the member will be using Trisenox (arsenic trioxide) for induction therapy, consolidation therapy, or relapsed disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### asenapine maleate - TABLET, SUBLINGUAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia/Bipolar I Disorder, manic or mixed episodes. The member must be utilizing asenapine for treatment of schizophrenia or bipolar I disorder. The member must have prior therapy or intolerance or contraindication to at least two of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## ASPARLAS - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on or following Asparlas (calaspargase pegol-mknl). Members with a history of serious thrombosis with prior asparaginase therapy. Members with a history of pancreatitis with prior asparaginase therapy. Members with a history of serious hemorrhagic events with prior asparaginase therapy. Members with total bilirubin more than 10 times the upper limit of normal.
Required Medical Information	Acute Lymphoblastic Leukemia (ALL): The member has a diagnosis of acute lymphoblastic leukemia (ALL) AND The member will be using Asparlas (calaspargase pegol-mknl) as a component of a multi-agent chemotherapy regimen.
Age Restriction	The age of the member is less than or equal to 21 years.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA
Part B Prerequisite	0

#### ATROVENT HFA - HFA AEROSOL WITH ADAPTER (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Obstructive Pulmonary Disease (COPD): Diagnosis of Chronic Obstructive Pulmonary Disease (COPD), including chronic bronchitis and emphysema. The member has had previous treatment, contraindication, or intolerance to Spiriva (i.e. Spiriva Handihaler, Spiriva Respimat).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### AUGTYRO - CAPSULE

PA Criteria	Criteria Details
PA Chiena	
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	ROS1 Positive NSCLC: Member has diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND Member has disease which is ROS-1 rearrangement(s) positive AND Member will be using Augtyro (repotrectinib) as monotherapy. NTRK Gene Fusion- Positive Solid Tumors: The member has a diagnosis of solid tumors which are metastatic OR the member is not a candidate for surgical resection AND The member has a documented neurotrophic tyrosine receptor kinase (NTRK) gene fusion AND The members disease has progressed following treatment or does not have satisfactory alternative therapy options AND Member will be using Augtyro (repotrectinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### AUSTEDO - TABLET

	1
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	TD: The member is utilizing Austedo (deutetrabenazine) or Austedo XR for the treatment of tardive dyskinesia that is associated with the use of dopamine receptor blocking agents AND Symptoms persist despite one of the following: Discontinuation or reduction in dose of dopamine blocking agent(s) OR Discontinuation or reduction in dose of dopamine blocking agent(s) is not possible. OR the member is utilizing Austedo (deutetrabenazine) or Austedo XR for the treatment of TD that is not associated with other medication therapies (e.g. dopamine receptor- blocking agents). Chorea with HD: Diagnosis of chorea associated with Huntington's disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### AUSTEDO XR - TABLET, EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	TD: The member is utilizing Austedo (deutetrabenazine) or Austedo XR for the treatment of tardive dyskinesia that is associated with the use of dopamine receptor blocking agents AND Symptoms persist despite one of the following: Discontinuation or reduction in dose of dopamine blocking agent(s) OR Discontinuation or reduction in dose of dopamine blocking agent(s) is not possible. OR the member is utilizing Austedo (deutetrabenazine) or Austedo XR for the treatment of TD that is not associated with other medication therapies (e.g. dopamine receptor- blocking agents). Chorea with HD: Diagnosis of chorea associated with Huntington's disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### AUSTEDO XR TITRATION KT(WK1-4) - TABLET, EXTENDED RELEASE 24 HR DOSE PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	TD: The member is utilizing Austedo (deutetrabenazine) or Austedo XR for the treatment of tardive dyskinesia that is associated with the use of dopamine receptor blocking agents AND Symptoms persist despite one of the following: Discontinuation or reduction in dose of dopamine blocking agent(s) OR Discontinuation or reduction in dose of dopamine blocking agent(s) is not possible. OR the member is utilizing Austedo (deutetrabenazine) or Austedo XR for the treatment of TD that is not associated with other medication therapies (e.g. dopamine receptor- blocking agents). Chorea with HD: Diagnosis of chorea associated with Huntington's disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### AUVELITY - TABLET, IMMED, EXTENDED RELEASE, BIPHASIC

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Major Depressive Disorder: The member has a clinical diagnosis of major depressive disorder (MDD) as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND the member has had prior therapy, contraindication, or intolerance to at least two different antidepressants of adequate dose (i.e. as determined by the treating provider based on individual patient characteristics) and duration (i.e. at least 8 weeks for each antidepressant) from the following: generic SSRI (e.g., citalopram, fluoxetine, paroxetine, or sertraline), SNRI (e.g., venlafaxine or duloxetine), bupropion OR mirtazapine.
Age Restriction	The member is 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### AVMAPKI-FAKZYNJA - COMBINATION PACKAGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Avmapki (avutometinib)-Fakzynja (defactinib).
Required Medical Information	Ovarian Cancer: The member has a diagnosis of recurrent low-grade serous ovarian cancer (LGSOC) AND The disease is documented as KRAS mutation-positive AND The member has received previous systemic therapy AND Avmapki (avutometinib) will be used in combination with Fakzynja (defactinib).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## AXTLE - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Part B Prerequisite	Pending CMS Review

#### AYVAKIT - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Ayvakit (avapritinib).
Required Medical Information	Gastrointestinal Stromal tumor. The member has documented PDGFRA exon 18 mutation-positive unresectable or metastatic gastrointestinal stromal tumor (including PDGFRA D842V) AND Ayvakit (avapritinib) will be given as monotherapy. Advanced systemic mastocytosis: The member has a diagnosis of advanced systemic mastocytosis (AdvSM), including systemic mastocytosis with an associated hematological neoplasm and mast cell leukemia AND Avyakit is not recommended for the treatment of members with AdvSM with platelet counts of less than 50 X 109 /L AND Ayvakit (avapritinib) is administered as monotherapy. Indolent Systemic Mastocytosis (ISM). The member has a diagnosis of Indolent Systemic Mastocytosis (ISM) AND is not recommended for treatment of members with documented platelet counts of less than 50 X 109 /L AND Ayvakit (avapritinib) is administered as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

## azacitidine - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Myelodysplastic Syndromes. The member has a diagnosis of myelodysplastic syndrome AND one of the following scenarios apply: The member has a Revised International Prognostic Scoring System (IPSS-R) of higher risk disease (i.e. intermediate, high, very high) OR The member has a Revised International Prognostic Scoring System (IPSS-R) of lower risk disease (i.e. very low, low, or intermediate) AND one of the following sets of criteria applies: Clinically relevant thrombocytopenia, neutropenia, or increased marrow blasts OR Member has symptomatic anemia AND No 5q deletion AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND Serum erythropoietin levels less than or equal to 500 mU/mL AND An inadequate response to erythropoietins alone or in combination with Revlimid (lenalidomide) AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND 5q deletion AND An inadequate response to erythropoietin AND An inadequate response to immunosuppressive therapy OR Member has Symptomatic anemia AND 5q deletion AND An inadequate response or intolerance to Revlimid (lenalidomide) AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy. Myeloproliferative Neoplasms: The member has a diagnosis of myelofibrosis (MF)-accelerated phase or MF- blast phase/acute myeloid leukemia. Acute Myelogenous Leukemia (AML). The member has a diagnosis of AML.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **BALVERSA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Urothelial Cancer: The member has a diagnosis of locally advanced or metastatic urothelial carcinoma AND the member has identification of a susceptible FGFR3 genetic alteration documented in the medical record [e.g., FGFR3 gene mutations (R248C, S249C, G370C, Y373C), FGFR3 gene fusions (FGFR3-TACC3v1, FGFR3-TACCv3, FGFR3-TACC3, FGFR3-BAIAP2L1)] AND the member will be using Balversa (erdafitinib) as a single agent for subsequent therapy after disease progression during or following at least one prior line of systemic therapy, including a PD-1 (Programmed cell death protein 1) or PD-L1 (Programmed death- ligand 1) inhibitor [e.g., avelumab, pembrolizumab] (if eligible).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

## BAVENCIO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following PD-1/PD-L1 therapy (e.g Keytruda, Opdivo, Tecentriq, Imfinzi).
Required Medical Information	Merkel Cell Carcinoma (Adults). The member has a diagnosis of metastatic Merkel cell carcinoma AND Member will be using Bavencio as monotherapy. Merkel Cell Carcinoma (Pediatrics). The member has a diagnosis of metastatic Merkel cell carcinoma AND Member will be using Bavencio as monotherapy. Urothelial Cancer. The member has a diagnosis of locally advanced or metastatic urothelial cancer AND the member will be using Bavencio (avelumab) as monotherapy AND One of the following apply: The member will be using Bavencio (avelumab) as second or subsequent line systemic therapy OR the member has had disease progression within 12 months of neoadjuvant or adjuvant chemotherapy OR The member will be using Bavencio (avelumab) as maintenance treatment if there is no disease progression with first-line platinum-containing chemotherapy. Renal Cell Carcinoma. The member has a diagnosis of advanced or metastatic renal cell carcinoma AND Bavencio (avelumab) will be given in combination with Inlyta (axitinib) as first-line therapy.
Age Restriction	Pediatric Merkel Cell Carcinoma - member must be 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

## BELEODAQ - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Beleodaq (belinostat). Members on concomitant Istodax (romidepsin), Zolinza (vorinostat), or Folotyn (pralatrexate) therapy.
Required Medical Information	Peripheral T-Cell Lymphoma (PTCL). The member must have a diagnosis of relapsed OR refractory peripheral T-cell lymphoma (PTCL).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six month duration
Other Criteria	NA
Part B Prerequisite	0

### bendamustine - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who experience disease progression on bendamustine containing regimens.
Required Medical Information	Chronic Lymphocytic Leukemia (CLL). The member has a diagnosis of CLL AND bendamustine is being used for relapsed or refractory disease or as first line therapy. Multiple Myeloma (MM). The member has a diagnosis of MM AND bendamustine is being used for disease relapse or for progressive or refractory disease. Non-Hodgkin's Lymphoma: The member has a diagnosis of follicular lymphoma, gastric MALT lymphoma or nongastric MALT lymphoma and is using Bendamustine. The member has a diagnosis of mantle cell lymphoma and bendamustine is being used as one of the following: Less aggressive induction therapy OR Second-line therapy for relapsed, refractory or progressive disease. The member has a diagnosis of primary cutaneous B-cell lymphoma (primary cutaneous marginal zone or follicle center B-cell lymphoma) and bendamustine is being used as a single agent or in combination with a rituximab product in one of the following: Refractory generalized cutaneous disease OR generalized extracutaneous disease as initial therapy or for relapse. The member has a diagnosis of splenic marginal zone lymphoma and bendamustine is being used as one of the following: First-line therapy for disease progression following initial treatment for splenomegaly OR Second-line or subsequent therapy for progressive disease. The member has a diagnosis of AIDS-related B-cell lymphoma and bendamustine is being used as second-line therapy or subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	Waldenstroms Macroglobulinemia: The member has Waldenstroms macroglobulinemia or lymphoplasmacytic lymphoma and bendamustine is being used as one of the following: Primary therapy OR Progressive or relapsed disease. Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin lymphoma AND bendamustine will be used as subsequent therapy for relapsed or refractory disease.
Part B Prerequisite	0

## BENLYSTA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Severe active central nervous system lupus.
Required Medical Information	Systemic Lupus Erythematosus (SLE). The member must have a diagnosis of active systemic lupus erythematosus (SLE). The member must be auto-antibody positive in the absence of any drugs for SLE defined as: ANA titer greater than or equal 1:80 or anti-dsDNA level greater than or equal 30 l/mL. The member must be utilizing Benlysta (belimumab) in combination with standard treatment regimens for SLE which may include: corticosteroids (e.g. prednisone), hydroxychloroquine, azathioprine. Lupus Nephritis: The member must be utilizing Benlysta in combination with standard therapy (e.g. corticosteroids with mycophenolate or cyclophosphamide).
Age Restriction	Lupus Nephritis: The member is 5 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# BESPONSA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on or following Besponsa (inotuzumab ozogamicin)
Required Medical Information	Acute Lymphoblastic Leukemia: The member has a diagnosis of B-cell precursor acute lymphoblastic leukemia (ALL)AND The member has relapsed or refractory disease AND The member has documented CD22 blasts found in bone marrow or peripheral blood AND The member will be using Besponsa (inotuzumab ozogamicin) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Six month durations (up to a maximum of 6 cycles)
Other Criteria	NA
Part B Prerequisite	0

## BESREMI - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with hepatic decompensation (Child-Pugh score greater than 6 [class B and C]). Members that have experienced disease progression while on Besremi (ropeginterferon alfa-2b-njft). Members with existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation or suicide attempt. Members that are immunosuppressed transplant recipients. Members with Hypersensitivity to interferon or to any component of Besremi (ropeginterferon alfa-2b- njft). Members with history or presence of active serious or untreated autoimmune disease.
Required Medical Information	Polycythemia Vera: The member has a diagnosis of Polycythemia Vera.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **BETASERON - KIT**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### bexarotene - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that are pregnant.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). (bexarotene capsules). The member will be using bexarotene as primary treatment OR Member has experienced disease progression, contraindication, or intolerance to at least one prior systemic therapy for cutaneous manifestations of cutaneous T-cell lymphoma. Cutaneous T-cell Lymphoma. (bexarotene 1% topical gel/jelly). The member will be using bexarotene as primary treatment OR Member has experienced disease progression, contraindications, or intolerance to at least one prior CTCL therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## BIZENGRI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on Bizengri (zenocutuzumab-zbco).
Required Medical Information	Non-Small Cell Lung Cancer [NSCLC]: NRG1 Gene Fusion Positive (NRG1 +): The member has a diagnosis of advanced, unresectable or metastatic non-small cell lung cancer [NSCLC] AND The disease is documented as neuregulin 1 (NRG1) gene fusion positive AND The member has previously been treated with at least one prior line of systemic therapy AND Bizengri (zenocutuzumab-zbco) will be given as monotherapy. Pancreatic Adenocarcinoma: NRG1 Gene Fusion Positive (NRG1 +) AND The member has a diagnosis of advanced, unresectable or metastatic pancreatic adenocarcinoma AND The disease is documented as neuregulin 1 (NRG1) gene fusion positive AND The member has previously been treated with at least one prior line of systemic therapy AND Bizengri (zenocutuzumab-zbco) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## BORTEZOMIB - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on bortezomib.
Required Medical Information	Mantle Cell Lymphoma (MCL): The member has a diagnosis of Mantle Cell Lymphoma(MCL). Multiple Myeloma. The member has a diagnosis of Multiple Myeloma. Waldenström's Macroglobulinemia. The member has a diagnosis of Waldenström's macroglobulinemia AND Velcade (bortezomib) is being used for primary therapy, progressive or relapsed disease or salvage therapy for disease that does not respond to primary therapy AND Velcade (bortezomib) is being used as monotherapy, in combination with Dexamethasone, or in combination with a rituximab product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### **BOSULIF - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Bosulif (bosutinib). The member has one of the following mutations: T315I, V299L, G250E, or F317L.
Required Medical Information	Chronic Myelogenous Leukemia. The member has a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (CML) AND One of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated and one of the following applies: Intermediate- or high-risk score for disease progression OR Low risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib OR The member has a diagnosis of chronic phase CML that has received previous treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **BRAFTOVI - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Tafinlar (dabrafenib), or Mekinist (trametinib) OR Members that have experienced disease progression while on prior anti- BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib)].
Required Medical Information	Melanoma - Unresectable or metastatic. The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Braftovi (encorafenib) in combination with Mektovi (binimetinib). Colorectal Cancer - [Braftovi (encorafenib) requests only]: The member has documented BRAFV600E metastatic colorectal cancer and progressive disease on prior therapy AND Braftovi (encorafenib) will be given in combination with Erbitux (cetuximab) OR The member has documented BRAFV600E metastatic colorectal cancer AND Braftovi (encorafenib) will be given in combination with Erbitux (cetuximab) and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin). Metastatic non- small cell lung cancer: The member has documented BRAF V600E metastatic non-small cell lung cancer (NSCLC) AND The member will be using Braftovi (encorafenib) in combination with Mektovi (binimetinib).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month durations
Other Criteria	
Part B Prerequisite	0

## BRIVIACT - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: Member has a diagnosis of partial-onset (focal) seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **BRUKINSA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Brukinsa (zanubrutinib).
Required Medical Information	Mantle cell lymphoma. The member has a diagnosis of mantle cell lymphoma AND The member has received at least one prior therapy AND The member will be using Brukinsa (zanubrutinib) as monotherapy. Marginal Zone Lymphoma: The member has a diagnosis of marginal zone lymphoma (MZL) AND The member is using Brukinsa (zanubrutinib) as second line or subsequent for refractory or progressive disease AND The member has received at least one regimen containing anti-CD20 product (e.g. rituximab product) AND The member will be using Brukinsa (zanubrutinib) as monotherapy. Waldenstroms Macroglobulinemia: The member has a diagnosis of Waldenstroms macroglobulinemia (WM) AND the member will be using Brukinsa (zanubrutinib) as monotherapy. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). Follicular Lymphoma: The member has a diagnosis of relapsed or refractory follicular lymphoma AND the member has had 2 or more previous lines of systemic therapy AND Brukinsa (zanubrutinib) will be used in combination with obinutuzumab.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### budesonide - TABLET, DELAYED AND EXTENDED RELEASE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Mild to moderate active ulcerative colitis: The member must have a diagnosis of mild to moderate active ulcerative colitis AND the member must have had previous treatment or intolerance to at least two of the following: sulfasalazine, balsalazide capsules, mesalamine enema or mesalamine 0.375g extended-release.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### buprenorphine - PATCH, TRANSDERMAL WEEKLY

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Management of pain severe enough to require daily, around-the-clock, long-term opioid treatment AND has tried at least 1 alternative therapy (e.g. non-opioid analgesics, or immediate-release opioids, or extended- release opioids).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### CABOMETYX - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Hepatocellular carcinoma, Renal cell carcinoma, and Thyroid cancer: Member experiences disease progression on cabozantinib.
Required Medical Information	Renal cell carcinoma: The member has advanced renal cell carcinoma AND one of the following applies: the member will be using Cabometyx (cabozanitinib) as monotherapy OR the member will be using Cabometyx (cabozanitinib) in combination with Opdivo (nivolumab) as first line therapy. Hepatocellular carcinoma. The member has a diagnosis of hepatocellular carcinoma AND The member has been previously treated with a first line therapy (e.g., sorafenib) AND Cabometyx (cabozantinib) will be given as monotherapy. Thyroid Cancer: The member has a diagnosis of locally advanced or metastatic differentiated thyroid cancer AND Member has experienced disease progression following prior anti-VEGF targeted therapy AND Member is radioactive iodine refractory or ineligible AND Cabometyx (cabozantinib) will be administered as monotherapy. Neuroendocrine Tumors (NETs): The member has a diagnosis of unresectable, locally advanced, or metastatic, well-differentiated neuroendocrine tumor (i.e., pNET and epNET).
Age Restriction	Thyroid Cancer and Neuroendocrine Tumors (NETs): Member is 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### calcipotriene - CREAM (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Psoriasis: The member must have a diagnosis of plaque psoriasis AND has had previous treatment, contraindication or intolerance with a high potency topical corticosteroid (e.g. triamcinolone 0.5%, betamethasone dipropionate/dipropionate augmented, or clobetasol).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## CALQUENCE (ACALABRUTINIB MAL) - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Calquence (acalabrutinib).
Required Medical Information	Mantle Cell Lymphoma: The member has a diagnosis of mantle cell lymphoma AND One of the following: the member has received at least one prior therapy and the member will be using Calquence (acalabrutinib) as monotherapy OR The member has previously untreated mantle cell lymphoma and member is ineligible for autologous hematopoietic stem cell transplantation (HSCT) and Calquence (acalabrutinib) will be used in combination with bendamustine and a rituximab product, followed by maintenance Calquence (acalabrutinib) with or without a rituximab product. Chronic lymphocytic leukemia (CLL) / Small lymphocytic lymphoma (SLL): member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **CAPLYTA - CAPSULE**

	-
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia. The member must have a diagnosis of schizophrenia AND The member must have documentation of prior therapy, intolerance, or contraindication to at least two of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I or II Disorder (Bipolar Depression): The member must have a diagnosis of bipolar I or II disorder (bipolar depression) AND the member must have documentation of prior therapy, intolerance, or contraindication to quetiapine and at least one of the following: olanzapine, or lurasidone.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **CAPRELSA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Vandetanib.
Required Medical Information	Thyroid Cancer. The member has a diagnosis of locally advanced or metastatic medullary thyroid cancer AND The member has symptomatic or progressive disease OR the member has a diagnosis of symptomatic iodine refractory follicular carcinoma or Hurthle cell carcinoma or papillary carcinoma AND unresectable recurrent or persistent locoregional disease or metastatic disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	3 months duration
Other Criteria	
Part B Prerequisite	0

### carglumic acid - TABLET, DISPERSIBLE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute or chronic hyperammonemia due to NAGS deficiency: the member has acute or chronic hyperammonemia due to deficiency of hepatic enzyme N-acetylglutamate synthase (NAGS). Acute hyperammonemia due to PAA or MMA deficiency: the member has acute hyperammonemia due to propionic acidemia (PA) or methylmalonic acidemia (MMA).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### CAYSTON - VIAL, NEBULIZER (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Patients with a forced expiratory volume in one second (FEV1) less than 25% or greater than 75% predicted. Patients colonized with Burkholderia cepacia.
Required Medical Information	Cystic Fibrosis. The member must have a diagnosis of cystic fibrosis (CF). The member is colonized with Pseudomonas aeruginosa. The member must have a short or long-acting beta-agonist bronchodilator (e.g. albuterol or formoterol), and will be utilized prior to Cayston.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year duration
Other Criteria	
Part B Prerequisite	0

### CHORIONIC GONADOTROPIN, HUMAN - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Obesity, Female or male infertility, Erectile Dysfunction, Precocious puberty, Prostatic carcinoma or other androgen-dependent neoplasm.
Required Medical Information	NA
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

### clobazam - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS) AND Onfi (clobazam) will be used in combination with at least one other drug for controlling seizures AND The member has been unable to achieve seizure control with at least one other drug used for the adjunctive treatment of Lennox- Gastaut syndrome (e.g., lamotrigine, rufinamide, topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### clozapine - TABLET, DISINTEGRATING

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must be using clozapine orally disintegrating tablet for treatment-resistant schizophrenia. The member must have had prior therapy or intolerance to generic clozapine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **COBENFY - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Urinary retention. Moderate or severe hepatic impairment. Gastric retention. Untreated narrow-angle glaucoma.
Required Medical Information	Schizophrenia: The member will be using Cobenfy for the treatment of schizophrenia AND The member has tried or cannot use at least two of the following generic atypical antipsychotics: olanzapine, risperidone, aripiprazole, quetiapine, lurasidone, or ziprasidone.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### COBENFY STARTER PACK - CAPSULE, DOSE PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Urinary retention. Moderate or severe hepatic impairment. Gastric retention. Untreated narrow-angle glaucoma.
Required Medical Information	Schizophrenia: The member will be using Cobenfy for the treatment of schizophrenia AND The member has tried or cannot use at least two of the following generic atypical antipsychotics: olanzapine, risperidone, aripiprazole, quetiapine, lurasidone, or ziprasidone.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# COLUMVI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member experienced disease progression on Columvi (glofitamab- gxbm) CD20-directed CD3 T-cell engager.
Required Medical Information	Large B-cell Lymphoma (relapsed/refractory): The member has a diagnosis of diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) OR large B-cell lymphoma (LBCL) arising from follicular lymphoma AND the member has received two or more prior lines of systemic therapy AND Columvi (glofitamab-gxbm) will be used as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **COMETRIQ - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Cometriq (cabozantinib).
Required Medical Information	Metastatic Medullary Thyroid Carcinoma. The member has a diagnosis of progressive, metastatic medullary thyroid carcinoma MTC.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	six month duration
Other Criteria	
Part B Prerequisite	0

#### CONTRAVE - TABLET, EXTENDED RELEASE

	Oritoria Dataila
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Weight Management: Member is prescribed Contrave as an adjunct to a reduced-carlorie diet and increased physical activity for chronic weight management AND Upon initiation of treatment with obesity medication, Body Mass Index (BMI) is at Least 30 kg/m2 (obese) OR 27 kg/m2 (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, dyslipidemia, type 2 diabetes) AND Member will be evaluated by prescribing physician to determine if at least 5% of baseline body weight has been lost at 12 weeks on maintenance dosage (16 weeks total) and at least every 6 months thereafter for continued treatment with obesity medication.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# COPAXONE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### **COPIKTRA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following a PI3K inhibitor (e.g. idelalisib, copanlisib, duvelisib).
Required Medical Information	Chronic lymphocytic leukemia. The member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) AND the member has relapsed or refractory disease AND The member will be using Copiktra (duvelisib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## COSENTYX - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis- related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti- inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Hidradenitis suppurativa: The member must have a diagnosis of moderate to severe hidradenitis suppurativa.
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, Non-radiographic axial spondyloarthritis, and Hidradenitis suppurativa: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis- related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## COSENTYX (2 SYRINGES) - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis- related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti- inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Hidradenitis suppurativa: The member must have a diagnosis of moderate to severe hidradenitis suppurativa.
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, Non-radiographic axial spondyloarthritis, and Hidradenitis suppurativa: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis- related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## COSENTYX PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis- related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti- inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Hidradenitis suppurativa: The member must have a diagnosis of moderate to severe hidradenitis suppurativa.
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, Non-radiographic axial spondyloarthritis, and Hidradenitis suppurativa: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis- related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# COSENTYX PEN (2 PENS) - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis- related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti- inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Hidradenitis suppurativa: The member must have a diagnosis of moderate to severe hidradenitis suppurativa.
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, Non-radiographic axial spondyloarthritis, and Hidradenitis suppurativa: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis- related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## COSENTYX UNOREADY PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Non-radiographic Axial Spondyloarthritis: The member has a diagnosis of non-radiographic axial spondyloarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance with a nonsteroidal anti-inflammatory drug (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Active Enthesitis- related Juvenile Idiopathic Arthritis: The member has a diagnosis of active enthesitis-related arthritis (ERA) AND the member has had prior therapy, contraindication, or intolerance with a non-steroidal anti- inflammatory drugs (NSAID) (e.g. ibuprofen, meloxicam, naproxen). Hidradenitis suppurativa: The member must have a diagnosis of moderate to severe hidradenitis suppurativa.
Age Restriction	Plaque Psoriasis: Member must be 6 years of age or older. Ankylosing Spondylitis, Non-radiographic axial spondyloarthritis, and Hidradenitis suppurativa: Member must be 18 years of age or older. Psoriatic Arthritis: member must be 2 years of age or older. Active Enthesitis- related Juvenile Idiopathic Arthritis: member must be 4 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **COTELLIC - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Melanoma indication only: Members on Cotellic as a single agent. Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda(pembrolizumab), Tafinlar (dabrafenib), Mekinist (trametinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Cotellic. Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib)].
Required Medical Information	Melanoma: The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Cotellic (cobimetinib) in combination with Zelboraf(vemurafenib). Histiocytic Neoplasms: the member has a diagnosis of histiocytic neoplasms AND the member will be using Cotellic (cobimetinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

# CYRAMZA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Cyramza (ramucirumab).
Required Medical Information	Gastric Cancer: member has a diagnosis of advanced or metastatic gastric cancer or gastro-esophageal adenocarcinoma AND the member has disease progression or intolerance on or after prior therapy with platinum-based or fluoropyrimidine-based chemotherapy AND Cyramza (ramucirumab) will be used as subsequent therapy AND will be used as monotherapy or in combination with paclitaxel. Non-Small Cell Lung Cancer: The member has a diagnosis of metastatic non-small cell lung cancer AND The member has disease progression or intolerance on or after prior therapy with platinum-based chemotherapy AND For members with EGFR (epidermal growth factor receptor) or ALK (anaplastic lymphoma kinase) genomic aberrations: the member has disease progression on FDA-approved therapy for these aberrations and Cyramza will be used in combination with Docetaxel OR member has documented epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations AND Cyramza (ramucirumab) is given in combo with erlotinib as first line therapy. Colorectal Cancer: The member has a diagnosis of unresectable or metastatic colorectal cancer AND Cyramza (ramucirumab) will be given as primary treatment in combination with FOLFIRI (fluorouracil, leucovorin calcium, and oxaliplatin) or CapeOX (capecitabine, oxaliplatin) as adjuvant therapy has been given OR The member has disease progression on or after prior therapy with a bevacizumab product, oxaliplatin, and a fluoropyrimidine (e.g. 5-fluorouracil, capecitabine) AND Cyramza is given in combination with FOLFIRI (rimotecan, folinic acid, and 5-fluorouracil) or irinotecan as therapy after first progression of disease if irinotecan was not previously given.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration

## CYRAMZA - VIAL (ML)

Other Criteria	Esophageal Cancer: The member has a diagnosis of unresectable locally advanced, recurrent, or metastatic esophageal adenocarcinoma AND Cyramza will be used as second or subsequent line therapy with or without paclitaxel. Hepatocellular Carcinoma: The member has a diagnosis of metastatic or unresectable hepatocellular carcinoma AND the member has received prior treatment with a first line therapy (e.g.,sorafenib) AND the member has alpha fetoprotein greater than or equal to 400 ng/ml AND Cyramza (ramucirumab) will be given as a single agent as subsequent therapy.
Part B Prerequisite	0

#### **CYSTARAN - DROPS**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Cystinosis: The member has a diagnosis of cystinosis AND The member is using cysteamine ophthalmic solution in the treatment of corneal cystine crystal accumulation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

## dalfampridine - TABLET, EXTENDED RELEASE 12 HR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	History of seizure disorder. Moderate to severe renal impairment (CrCl 50ml/min or less).
Required Medical Information	Multiple Sclerosis: Member has a diagnosis of multiple sclerosis AND Patient must be ambulatory AND The member has evidence of significant walking impairment related to multiple sclerosis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## DANYELZA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members receiving Danyelza (naxitamab) as monotherapy. Members that have experienced disease progression while on Danyelza (naxitamabgqgk).
Required Medical Information	Relapsed or Refractory Neuroblastoma: The member has a diagnosis of relapsed or refractory high-risk neuroblastoma AND The disease is in the bone or bone marrow AND The member has achieved a partial or minor response or stable disease to prior therapy AND Danyelza (naxitamab-gqgk) will be used in combination with Leukine (sargramostim).
Age Restriction	The member is 1 year of age and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### DANZITEN - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on any nilotinib (e.g. Tasigna, Danziten).
Required Medical Information	Chronic Myeloid Leukemia: The member has a diagnosis of Philadelphia Chromosome positive (Ph+) chronic myeloid leukemia (CML) AND One of the following: CML is in chronic phase OR CML is accelerated phase and if accelerated phase member is resistant to or intolerant to prior therapy that included imatinib.
Age Restriction	The member is 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## DARZALEX - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while taking Darzalex (daratumumab).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member will be using Darzalex (daratumumab) for newly diagnosed disease AND the member is ineligible for autologous stem cell transplant AND the member will be using Darzalex (daratumumab) in combination with bortezomib, melphalan, and prednisone OR the member will be using Darzalex in combination with lenalidomide and dexamethasone OR the member is eligible for autologous stem cell transplant AND the member will be using Darzalex in combination with bortezomib, thalidomide, and dexamethasone OR the member will be using Darzalex (daratumumab) for relapsed, progressive, or refractory disease in one of the following scenarios: The member will be using Darzalex (daratumumab) in combination with Pomalyst (pomalidomide) and dexamethasone AND the member has received at least two prior therapies, including lenalidomide and a proteasome inhibitor (e.g. bortezomib, carfilzomib, or ixazomib) OR The member will be using Darzalex (daratumumab) in combination with Velcade (bortezomib) and dexamethasone OR The member will be using Darzalex (daratumumab) in combination with Revlimid (lenalidomide) and dexamethasone OR the member will be using Darzalex (daratumumab) in combination with Revlimid (lenalidomide) and dexamethasone OR the member will be using Darzalex (daratumumab) in combination with Revlimid (lenalidomide) and dexamethasone OR the member will be using Darzalex (daratumumab) in combination with Revlimid (lenalidomide) and dexamethasone OR the member has received at least three prior lines of therapy, which must have included a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide) OR The member is double-refractory to a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide). Omission of corticosteroid from regimen is allowed if intolerance/contraindication.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## DARZALEX FASPRO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while taking daratumumab. Members who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB (Applicable to Light chain (AL) amyloidosis indication only).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member will be using Darzalex (daratumumab) Faspro for newly diagnosed disease in one of the following scenarios AND the member is ineligible for autologous stem cell transplant AND the member will be using Darzalex Faspro in combination with bortezomib, melphalan, and prednisone OR the member will be using Darzalex Faspro in combination with lenalidomide and dexamethasone OR the member is eligible for autologous stem cell transplant AND the member will be using in combination with bortezomib, thalidomide, and dexamethasone OR the member will be using in combination with bortezomib, lenalidomide, and dexamethasone OR the member will be using Darzalex Faspro for relapsed or progressive disease in one of the following scenarios: in combination with Velcade (bortezomib) and dexamethasone OR in combination with Kyprolis (carfilzomib) and dexamethasone OR in combination with Pomalyst (pomalidomide) and dexamethasone OR in combination with Promalyst (pomalidomide) and dexamethasone OR as monotherapy and one of the following applies: The member has received at least three prior lines of therapy, which must have included a proteasome inhibitor (e.g. bortezomib) or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide) OR The member is double-refractory to a proteasome inhibitor (e.g. bortezomib or carfilzomib) and an immunomodulatory drug (e.g. thalidomide, lenalidomide, or pomalidomide). Omission of corticosteroid from regimen is allowed if intolerance/contraindication. Light Chain Amyloidosis: The member has a diagnosis of light chain amyloidosis AND The member will be using Darzalex Faspro for newly diagnosed disease AND The member will be using in combination with bortezomib, cyclophosphamide, and dexamethasone. Omission of corticosteroid from regimen is allowed if intolerance/contraindication.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	

## DARZALEX FASPRO - VIAL (ML)

Part B	0
Prerequisite	

#### dasatinib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on dasatinib. For ALL and CML: The member has one of the following mutations: T315I/A, F317L/V/I/C or V299L.
Required Medical Information	Chronic Myelogenous Leukemia (CML): The member has a diagnosis of Ph+ chronic myeloid leukemia (CML) and one of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated and one of the following applies: Intermediate- or high-risk score for disease progression OR Low risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib OR The member has a diagnosis of chronic phase CML that has received previous treatment. Acute Lymphoblastic Leukemia (ALL): The member has ALL (Philadelphia Chromosome positive) and dasatinib is being used for induction or consolidation treatment in combination with chemotherapy or corticosteroids OR treatment is for maintenance therapy or the treatment of members with resistance or intolerance to prior therapy. Advanced Gastrointestinal Stromal Tumor (GIST): The member has a diagnosis of advanced unresectable GIST. The member has progressive disease or is intolerant to prior therapy with Gleevec (imatinib) or Sutent (sunitinib) or Stivarga. [Pediatric] Chronic Myelogenous Leukemia (CML). The member has a diagnosis of acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL). AND the member has newly-diagnosed disease AND The member will be using dasatinib in combination with chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## DATROWAY - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on prior Datroway (datopotamab deruxtecan-dlnk).
Required Medical Information	Breast Cancer [HR-positive and HER2-negative]: The member has a diagnosis of unresectable or metastatic, hormone receptor [HR]-positive, human epidermal growth factor receptor 2 [HER2]-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer AND The member has received prior endocrine-based therapy AND The member has received at least one line of prior systemic chemotherapy in the unresectable or metastatic setting AND Datroway (datopotamab deruxtecan-dlnk) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **DAURISMO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression while on Daurismo (glasdegib).
Required Medical Information	Acute Myeloid Leukemia. The member has a diagnosis of newly- diagnosed acute myeloid leukemia (AML) AND One of the following applies: The member is age 75 years or older OR The member has comorbidities that preclude the use of intensive induction chemotherapy (e.g. severe cardiac disease, baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2, or baseline serum creatinine greater than 1.3 mg/dL) AND The member will be using Daurismo (glasdegib) in combination with low-dose Cytarabine. Acute Myeloid Leukemia - Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member will be using Daurismo (glasdegib) as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months) AND Daurismo (glasdegib) has not been administered continuously AND Daurismo (glasdegib) was not stopped due to the development of clinical resistance.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA
Part B Prerequisite	0

## decitabine - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Myelodysplastic Syndromes. The member has a diagnosis of myelodysplastic syndrome AND one of the following scenarios apply: The member has a Revised International Prognostic Scoring System (IPSS-R) of higher risk disease (i.e. intermediate, high, very high) OR The member has a Revised International Prognostic Scoring System (IPSS-R) of lower risk disease (i.e. very low, low, or intermediate) AND one of the following sets of criteria applies: Clinically relevant thrombocytopenia, neutropenia, or increased marrow blasts OR Member has symptomatic anemia AND No 5q deletion AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND Serum erythropoietin levels less than or equal to 500 mU/mL AND An inadequate response to erythropoietins alone or in combination with Revlimid (lenalidomide) AND An inadequate response or intolerance or contraindication to immunosuppressive therapy OR Member has Symptomatic anemia AND 5q deletion AND An inadequate response to erythropoietins alone or in combination with Revlimid (lenalidomide) AND An inadequate response or intolerance to Revlimid (lenalidomide) AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance to Revlimid (lenalidomide) AND Serum erythropoietin levels greater than 500 mU/mL AND An inadequate response or intolerance or contraindication to immunosuppressive therapy. Myeloproliferative Neoplasms: The member has a diagnosis of myelofibrosis (MF)-accelerated phase or MF- blast phase/acute myeloid leukemia. Acute Myelogenous Leukemia (AML). The member has a diagnosis of AML.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### deferasirox - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has platelet counts less than 50,000.
Required Medical Information	Chronic Iron Toxicity (hemosiderosis) Secondary to Transfusional Iron Overload. Initial Request: The Member must meet ALL of the following criteria: Diagnosis of chronic iron overload (hemosiderosis) secondary to multiple RBC transfusions. AND Ferritin level greater than 1000 mcg/L (ferritin should consistently be above 1000 mcg/L to necessitate treatment). Continuation of Therapy Request: The Member must meet ALL of the following criteria: Ferritin level must be consistently above 500mcg/L (deferasirox should be stopped if Ferritin level is consistently below 500 mcg/L.) Chronic iron overload in patients with non-transfusion dependent thalassemia (NTDT) syndromes. Initial Request: The member must meet ALL of the following criteria: The member has a diagnosis of chronic iron overload with non-transfusion dependent thalassemia (NTDT) syndrome AND The member has liver iron (Fe) concentration of at least 5mg/gm of liver dry weight AND The member has a serum ferritin greater than 300 mcg/L. Continuation of Therapy Request: The Member must meet ALL of the following criteria: Liver iron (Fe) concentration of at least 5mg/gm of liver dry weight AND Serum ferritin greater than 300 mcg/L.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial: Plan Year Duration. Reauthorization: Plan year duration.
Other Criteria	
Part B Prerequisite	0

#### **DIACOMIT - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of seizures associated with Dravet syndrome AND Diacomit is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member is refractory on current therapy (e.g experiencing generalized tonicclonic or clonic seizures within the past 28 days) AND The member is taking concomitant clobazam therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### diclofenac sodium - DROPS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Osteoarthritis. Member has a diagnosis of osteoarthritis of the knee(s) AND the member has had previous treatment, contraindication, or intolerance to at least two of the following prescription oral NSAIDs: diclofenac sodium, meloxicam tablets, naproxen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## diclofenac sodium - GEL (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Actinic Keratosis: The member has a diagnosis of actinic keratosis. The member has trial, intolerance, or contraindication to generic imiquimod 5% cream or topical fluorouracil.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### dihydroergotamine - AEROSOL, SPRAY WITH PUMP (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute treatment of moderate to severe migraine headaches with or without aura AND has had previous treatment, intolerance, or contraindication to two of the following: naproxen tablet, naratriptan tablet, rizatriptan tablet, sumatriptan tablet.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# dimethyl fumarate - CAPSULE, DELAYED RELEASE (ENTERIC COATED)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

## doxorubicin, peg-liposomal - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ovarian Cancer: The member has a diagnosis of persistent or recurrent ovarian cancer and one of the following applies: if platinum sensitive, in combination with carboplatin OR if platinum resistant, as a single agent or in combination with bevacizumab product OR The member has a diagnosis ovarian cancer and Liposomal doxorubicin will be used in combination with carboplatin and one of the following applies: perioperative treatment in members who are poor surgical candidates or low likelihood of optimal cytoreduction or adjuvant treatment or primary treatment in members with incomplete previous surgery or staging. Breast Cancer: The member has a diagnosis of recurrent or metastatic HER-2-negative breast cancer. Hodgkin Lymphoma: The member has a diagnosis of relapsed or refractory Hodgkins Lymphoma AND The member will be using liposomal doxorubicin as second-line or subsequent therapy. Kaposi's Sarcoma: The member has a diagnosis of AIDS-related Kaposi's sarcoma AND One of the following criteria applies: The member has had prior treatment, intolerance, or contraindication to prior systemic chemotherapy, or the member is using Liposomal doxorubicin as first line therapy. Multiple Myeloma: The member has a diagnosis of relapsed or refractory multiple myeloma AND The member will be using liposomal doxorubicin in combination with Velcade (bortezomib).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration

## doxorubicin, peg-liposomal - VIAL (ML)

Other Criteria	Non-Hodgkin's lymphoma: The member has a diagnosis of T-Cell Leukemia or Lymphoma AND Liposomal doxorubicin is given in combination with gemcitabine and vinorelbine and one of the following: for non-responders as first line therapy or for refractory disease after two primary treatment prior to proceeding to transplant OR The member has diagnosis of diffuse large B cell lymphoma AND Liposomal doxorubicin is given in combination with RCDOP (rituximab product, cyclophosphamide, vincristine and prednisone) in members with documented poor ventricular or very frail OR The member has a diagnosis of Mycosis Fungoides (MF)/Sezary Syndrome (SS) and liposomal doxorubicin is given and one of the following: primary treatment OR as combination therapy with gemcitabine and vinorelbine prior to proceeding to transplant OR The member has a diagnosis of relapsed or refractory peripheral T-cell lymphoma (not otherwise specified or enteropathy associated Tcell lymphoma) AND Liposomal doxorubicin is given as subsequent therapy in combination therapy with
Part B Prerequisite	gemcitabine and vinorelbine prior to proceeding to transplant.

#### DRIZALMA SPRINKLE - CAPSULE, DELAYED RELEASE SPRINKLE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Major Depressive Disorder, Generalized Anxiety Disorder, or Diabetic Peripheral Neuropathic Pain: The member has a diagnosis of Major Depressive Disorder (MDD), Generalized Anxiety Disorder (GAD), or Diabetic Peripheral Neuropathic Pain (DPNP). The member has prior therapy, intolerance, or contraindication with venlafaxine (IR or ER) AND duloxetine 20mg, 30mg or 60 mg (generic Cymbalta). Chronic Musculoskeletal Pain, Fibromyalgia: The member has a diagnosis of Chronic Musculoskeletal Pain or Fibromyalgia (FM). The member has prior therapy, intolerance, or contraindication with duloxetine 20mg, 30mg or 60 mg (generic Cymbalta).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### DUAVEE - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Treatment of moderate to severe vasomotor symptoms associated with menopause:Diagnosis of moderate to severe vasomotor symptoms associated with menopause AND The member must have had previous treatment, intolerance or contraindication to a SSRI [e.g. citalopram, fluoxetine, paroxetine hydrochloride] or venlafaxine. Prevention of osteoporosis: For the prevention of osteoporosis in a member who is postmenopausal AND the member must have had previous treatment, intolerance, or contraindication to either alendronate or Evista (raloxifene).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## DUPIXENT PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis: The member has a diagnosis of moderate to severe Atopic Dermatitis (e.g. erythema that is pink-red to deep or bright red, moderate to severe induration/population, frequent to incessant itching, frequent to nightly loss of sleep) AND The member has had previous treatment, intolerance to, or contraindication to one high potency topical corticosteroid (e.g. augmented betamethasone dipropionate 0.05%, clobetasol cream/gel/ointment, triamcinolone acetonide 0.5%) OR one topical calcineurin inhibitor (e.g. pimecrolimus cream or tacrolimus). Eosinophilic Esophagitis (EoE): Member must meet all of the following criteria: 15 kg (33 pounds) or higher, Diagnosis of eosinophilic esophagitis (EOE) identified by endoscopic biopsy with evidence of peak cell count of greater than or equal to 15 eosinophils per high power field in 2 or more biopsied esophageal regions, two or more episodes of dysphagia per week, unable to achieve adequate control of symptoms with one guideline directed therapy (e.g., generic high dose proton pump inhibitor OR topical corticosteroid). Chronic Spontaneous urticaria (CSU): Member has a diagnosis of chronic spontaneous urticaria AND Member has remained symptomatic despite at least 2 weeks of H1 antihistamine therapy, unless contraindicated AND Member will continue to receive H1 antihistamine therapy while on Dupixent, unless contraindicated.
Age Restriction	Atopic dermatitis: The member must be 6 months of age or older. Chronic rhinosinusitis with nasal polyposis and Chronic Spontaneous Urticaria: The member must be 12 years of age or older. Prurigo Nodularis and COPD with an eosinophilic phenotype: The member must be 18 years of age or older. Eosinophilic Esophagitis: 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## DUPIXENT PEN - PEN INJECTOR (ML)

Other Criteria	Moderate-to-severe asthma with an eosinophilic phenotypic or with oral corticosteroid dependent asthma: The member has a diagnosis of moderate-to-severe asthma AND The member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of: greater than or equal to 150 cells/uL at therapy initiation, OR greater than or equal to 300 cells/uL in the previous 12 months, OR The member has oral corticosteroid-dependent asthma AND The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy in combination with a long acting beta agonist (eg formoterol). Chronic Rhinosinusitis with Nasal Polyposis: The member must have a diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Dupixent (dupilumab) will be used in conjunction with a daily intranasal corticosteroid spray AND The member has been unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy. Prurigo Nodularis: member must have a liagnosis of Prurigo Nodularis. AND prescribed by or in consultation with a dermatologist, allergist, or immunologist AND unable to achieve adequate cortrol of symptoms with one moderate to super potent topical corticosteroid OR prescriber determines that treatment with a topical corticosteroid would be inappropriate. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype: The member has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype defined as an elevated peripheral blood eosinophil evel of greater than or equal to 300 cells/uL in the previous 12 months AND The member has been unable to achieve adequate control of OCPD while on an: Inhaled corticosteroid therapy in combination with a long-acting beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) OR LABA-LAMA therapy if inhaled corticosteroid centrandicated.
Part B	0
Prerequisite	

## DUPIXENT SYRINGE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis: The member has a diagnosis of moderate to severe Atopic Dermatitis (e.g. erythema that is pink-red to deep or bright red, moderate to severe induration/population, frequent to incessant itching, frequent to nightly loss of sleep) AND The member has had previous treatment, intolerance to, or contraindication to one high potency topical corticosteroid (e.g. augmented betamethasone dipropionate 0.05%, clobetasol cream/gel/ointment, triamcinolone acetonide 0.5%) OR one topical calcineurin inhibitor (e.g. pimecrolimus cream or tacrolimus). Eosinophilic Esophagitis (EoE): Member must meet all of the following criteria: 15 kg (33 pounds) or higher, Diagnosis of eosinophilic esophagitis (EOE) identified by endoscopic biopsy with evidence of peak cell count of greater than or equal to 15 eosinophils per high power field in 2 or more biopsied esophageal regions, two or more episodes of dysphagia per week, unable to achieve adequate control of symptoms with one guideline directed therapy (e.g., generic high dose proton pump inhibitor OR topical corticosteroid). Chronic Spontaneous Urticaria (CSU): Member has a diagnosis of chronic spontaneous urticaria AND Member has remained symptomatic despite at least 2 weeks of H1 antihistamine therapy, unless contraindicated AND Member will continue to receive H1 antihistamine therapy while on Dupixent, unless contraindicated.
Age Restriction	Atopic dermatitis: The member must be 6 months of age or older. Chronic rhinosinusitis with nasal polyposis and Chronic Spontaneous Urticaria: The member must be 12 years of age or older. Prurigo Nodularis and COPD with an eosinophilic phenotype: The member must be 18 years of age or older. Eosinophilic Esophagitis: 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## DUPIXENT SYRINGE - SYRINGE (ML)

Other Criteria	Moderate-to-severe asthma with an eosinophilic phenotypic or with oral corticosteroid dependent asthma: The member has a diagnosis of moderate-to-severe asthma AND The member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of: greater than or equal to 150 cells/uL at therapy initiation, OR greater than or equal to 300 cells/uL in the previous 12 months, OR The member has oral corticosteroid-dependent asthma AND The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy in combination with a long acting beta agonist (eg formoterol). Chronic Rhinosinusitis with Nasal Polyposis: The member must have a diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Dupixent (dupilumab) will be used in conjunction with a daily intranasal corticosteroid spray AND The member has been unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy. Prurigo Nodularis: member must meet all of the following criteria: diagnosis of Prurigo Nodularis, or immunologist AND unable to achieve adequate control of symptoms with an eosinophilic phenotype: The member has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype. The member has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype that no requal to 300 cells/uL in the previous 12 months AND The member has been unable to achieve adequate corticosteroid would be inappropriate. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype adefined as an elevated peripheral blood eosinophil level of greater than or equal to 300 cells/uL in the previous 12 months AND The member has been unable to achieve adequate control of COPD while on an: Inhaled corticosteroid therapy in combination with a long-acting muscarinic antagonist (LAMA) OR LABA-LAMA therapy if inhaled corticosteroids are contraindicated.
Part B Prerequisite	0

## EGRIFTA SV - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	HIV-Associated Lipodystrophy. The member must have a diagnosis of HIV-associated lipodystrophy. The member must utilize Egrifta (tesamorelin) to reduce excess fat for the abdominal area. The member must be/have been on a protease inhibitor (PI) and/or nucleoside reverse transcriptase inhibitor (NRTI).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **EGRIFTA WR - KIT**

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Part B Prerequisite	Pending CMS Review

## ELAHERE - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Elahere (mirvetuximab soravtansine-gynx).
Required Medical Information	Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (platinum-resistant disease): The member has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer AND The member has platinum-resistant disease AND The member has high levels of folate receptor alpha (FRa) expression (defined as greater than or equal to 75% tumor cells staining with 2+ intensity) AND The member has received at least one to three prior systemic treatment regimens AND The member is using Elahere (mirvetuximab soravtansine-gynx) as single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# ELELYSO - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Gaucher Disease. The member has a confirmed diagnosis of Type 1 Gaucher disease.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	Plan Year Duration.
Other Criteria	NA
Part B Prerequisite	0

## ELIGARD - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# ELIGARD (3 MONTH) - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# ELIGARD (4 MONTH) - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# ELIGARD (6 MONTH) - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.Should not be used in pregnancy.
Required Medical Information	The patient must have a diagnosis of advanced prostate cancer or has a high risk of disease recurrence. Invasive Breast Cancer. The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer. The patient must be pre or perimenopausal. Diagnosis of recurrent ovarian cancer (epithelial cell or ovarian stromal tumor).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

## ELREXFIO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on a bispecific B-cell maturation antigen (BCMA)- directed CD3 T-cell engager- containing regimen.
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member has relapsed/refractory disease AND The member has received at least four prior lines of therapy, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib), and an immunomodulatory agent (e.g. lenalidomide) AND The member is using Elrexfio (elranatamab-bcmm) as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## ELZONRIS - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN): The member has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN) according to World Health Organization (WHO) classification AND the member is able to be an inpatient for at least the first complete course of therapy plus an additional 24 hours for observation.
Age Restriction	The member must be 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

#### EMGALITY PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Migraine Prevention. Utilizing Emgality (galcanezumab) for the preventative treatment of migraines.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## EMGALITY SYRINGE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Episodic Cluster Headache: The member has been diagnosed with episodic cluster headaches as defined as having at least two cluster periods lasting from 7 days to 1 year, separated by pain free remission periods lasting at least 1 month AND the member has been unable to achieve a reduction in weekly cluster headache attack frequency with a trial of verapamil.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## EMGALITY SYRINGE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Migraine Prevention. Utilizing Emgality (galcanezumab) for the preventative treatment of migraines.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## EMPLICITI - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members with disease progression while on Empliciti (elotuzumab)
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND One of the following scenarios apply: The member has disease progression after receiving one to three prior lines of therapy AND Empliciti (elotuzumab) will be given in combination with lenalidomide (Revlimid) and dexamethasone OR in combination with bortezomib (Velcade) and dexamethasone OR The member has disease progression after receiving at least two prior therapies, including lenalidomide and a proteasome inhibitor AND Empliciti (elotuzumab) will be given in combination with pomalidomide (Pomalyst) and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA
Part B Prerequisite	0

## EMRELIS - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression Emrelis (telisotuzumab vedotin-tllv).
Required Medical Information	Non-small cell lung cancer (NSCLC) [Non-squamous]: The member has a diagnosis of locally advanced or metastatic non-squamous, EGFR wild-type, non-small cell lung cancer (NSCLC) AND The member has high c-Met protein overexpression positive disease, defined as 50% or more of tumor cells with strong (3+) staining (i.e., c-Met/MET greater than or equal to 50% IHC 3+), as determined by an FDA-approved test AND The member has received previous systemic therapy AND Emrelis (telisotuzumab vedotin-tllv) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### EMSAM - PATCH, TRANSDERMAL 24 HOURS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Major Depressive Disorder: The member is an adult with a clinical diagnosis of major depressive disorder (MDD) as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D). The member has had prior therapy, intolerance, or contraindication with a generic SSRI (e.g. citalopram, fluoxetine, paroxetine, or sertraline), generic SNRI (e.g. venlafaxine or duloxetine), a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) OR mirtazapine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## ENHERTU - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Enhertu (fam-trastuzumab deruxtecan-nxki)
Required Medical Information	HER2-Positive Breast cancer: The member has a diagnosis of unresectable or metastatic breast cancer AND The disease is human epidermal growth factor receptor 2 (HER2) positive AND The member has received prior anti-HER2 based regimens [e.g., Perjeta (pertuzumab)- based regimens, Kadcyla (ado-trastuzumab emtansine)] in the metastatic setting OR in the neoadjuvant or adjuvant setting and has developed disease reoccurrence and one of the following applies: during or within six months of completing therapy OR during or within twelve months of completing Perjeta-containing regimens. The member does not have symptomatic interstitial lung disease (ILD). Enhertu (fam- trastuzumab deruxtecan-nxki) will be given as monotherapy. Gastric or Gastroesophageal Junction Adenocarcinoma: The member has a diagnosis of locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma AND the disease is human epidermal growth factor receptor 2 (HER2) positive AND The member has received prior treatment with prior trastuzumab-based regimen AND The member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam- trastuzumab deruxtecan-nxki) will be given as monotherapy. HER2-Low Breast cancer: the member has a diagnosis of unresectable or metastatic breast cancer AND the disease is human epidermal growth factor receptor 2 (HER2) low (defined as IHC 1+ or IHC 2+/ISH-negative) AND the member has: received prior chemotherapy regimen(s) in the metastatic setting (e.g. capecitabine, Eribulin, gemcitabine, paclitaxel) OR developed disease recurrence during or within six months of completing adjuvant chemotherapy OR the member has documented hormone receptor (HR)-positive disease and has experienced disease progression on one or more endocrine therapies in the metastatic setting AND the member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## ENHERTU - VIAL (EA)

Other Criteria	HER2-Mutant Non-Small Cell Lung Cancer: the member has a diagnosis of unresectable or metastatic non-small cell lung cancer (NSCLC) AND NSCLC is documented (HER2 (ERBB2)) mutant AND the member has received a prior systemic therapy (e.g. platinum-based therapy, immunotherapy) AND the member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy. HER2-Positive Solid Tumors: The member has a diagnosis of an unresectable or metastatic solid tumor (e.g., bladder, biliary tract, cervical, colorectal, endometrial, ovarian, salivary gland cancer) AND The disease is human epidermal growth factor receptor 2 (HER2) positive [IHC 3+] AND The member has received prior systemic treatment and has no satisfactory alternative treatment options AND The member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy. HER2-Ultralow Breast Cancer: The member has a diagnosis of unresectable or metastatic breast cancer AND The disease is human epidermal growth factor receptor 2 (HER2) ultralow (IHC 0+, defined as IHC 0 with faint, partial membrane staining) AND The member has documented hormone receptor (HR)-positive disease and has experienced disease progression on one or more endocrine therapies in the metastatic setting AND The member does not have symptomatic interstitial lung disease (ILD) AND Enhertu (fam-trastuzumab deruxtecan-nxki) will be given as monotherapy.
Part B Prerequisite	0

#### ENVARSUS XR - TABLET, EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must have had a kidney transplant AND Must be using Envarsus XR for prophylaxis of organ rejection AND Must be using in combination with other immunosuppressants.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### **EPCLUSA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Hepatitis C Virus Genotypes: The member must have a diagnosis of chronic hepatitis C (HCV). For all genotypes, criteria will be applied consistent with current AASLD-IDSA guidance.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 weeks depending on disease state and genotype based on AASLD treatment guidelines for HCV.
Other Criteria	
Part B Prerequisite	0

#### EPIDIOLEX - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Dravet Syndrome: The member has a diagnosis of seizures associated with Dravet Syndrome AND Epidiolex (cannabidiol) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member has been unable to achieve seizure control with at least one other drug used for the treatment of Dravet Syndrome (e.g. clobazam, valproic acid, topiramate). Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut syndrome AND Epidiolex (cannabidiol) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member has been unable to achieve seizure control with at least one other drug used for the treatment of Lennox-Gastaut syndrome (e.g., valproic acid, lamotrigine, topiramate). Tuberous Sclerosis Complex: The member has a diagnosis of seizures associated with Tuberous Sclerosis Complex.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## EPKINLY - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has active central nervous system (CNS) involvement with lymphoma (DLBCL and High-grade B-cell Lymphoma only). The member experienced disease progression on Epkinly or CD20-directed CD3 T-cell engager.
Required Medical Information	B-cell Non-Hodgkin's Lymphoma. The member has a diagnosis of diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), including DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL) AND The member has received two or more prior lines of therapy AND Epkinly will be used as monotherapy. Follicular Lymphoma: The member has a diagnosis of follicular lymphoma AND the member has received two or more lines of systemic therapy AND Epkinly will be used as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **EPRONTIA - SOLUTION, ORAL**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Migraine Prophylaxis: Member is using for prophylaxis of migraine headache AND has had previous treatment with or intolerance to immediate release topiramate tablet or capsule AND has had previous treatment, intolerance, or contraindication with propranolol or timolol. Epilepsy Adjunctive Therapy: Member has a diagnosis of partial-onset (focal) seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) AND Member will use Eprontia (topiramate) in combination with at least one other drug for controlling seizures AND Member has tried or cannot use immediate- release topiramate tablet or capsule. Epilepsy Monotherapy: Member has a diagnosis of partial-onset (focal) seizures or primary generalized tonic-clonic seizures AND Member has tried or cannot use immediate- release topiramate tablet or capsule. Epilepsy Monotherapy: Member has a diagnosis of partial-onset (focal) seizures or primary generalized tonic-clonic seizures AND Member has tried or cannot use immediate release topiramate tablet or capsule.
Age Restriction	Migraine Prophylaxis: Member must be 12 years of age or older. Epilepsy indications: Member must be 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## ERBITUX - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with colorectal cancer (CRC) in which RAS mutation status is unknown [Applies to Colorectal Cancer [Wild-Type RAS; Wild-Type KRAS/NRAS]and Colorectal Cancer [KRAS G12C-mutated]. Member has had disease progression on Vectibix or Erbutux. [All Indications]
Required Medical Information	Colorectal Cancer [Wild-Type RAS; Wild-Type KRAS/NRAS]. The member has a diagnosis of advanced or metastatic colorectal cancer (mCRC) AND The member has colorectal cancer that is documented as wild-type, non-mutated KRAS and NRAS [wild-type RAS] AND Erbitux (cetuximab) will be used as one of the following: as monotherapy in members intolerant to irinotecan or who have experienced disease progression following therapy with both irinotecan and oxaliplatin based therapy OR in combination with irinotecan-based therapy OR in combination with fluorouracil based therapy (CAPEOX, FOLFOX, FOLFIRI). Head and Neck Cancer. The member has a diagnosis of locally or regionally advanced squamous cell head and neck cancer with concomitant XRT (radiation) OR The member has recurrent (including locoregional), unresectable, or metastatic squamous cell head and neck cancer and one of the following applies: Erbitux (cetuximab) will be given as monotherapy or Erbitux (cetuximab) will be given in combination with platinum agent OR Erbitux (cetuximab) will be given in combination with platinum agent OR Erbitux (cetuximab) will be given in combination with platinum-based therapy with 5-FU (fluorouracil). Colorectal Cancer [BRAF V600E-mutated]: The member has documented BRAF V600E metastatic colorectal cancer (mCRC) AND One of the following scenarios applies: The member has documented BRAF V600E metastatic colorectal cancer and progressive disease on prior therapy and Erbitux (cetuximab) will be given in combination with Braftovi (encorafenib) OR The member has documented BRAF V600E metastatic colorectal cancer and Erbitux (cetuximab) will be given in combination with Braftovi (encorafenib) and FOLFOX (fluorouracil, leucovorin, and oxaliplatin) regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## ERBITUX - VIAL (ML)

Other Criteria	Colorectal Cancer [KRAS G12C-mutated]. The member has a diagnosis of locally advanced or metastatic colorectal cancer (mCRC) AND The colorectal cancer (CRC) has a documented KRAS G12C mutation, as determined by an FDA-approved test AND The member has received prior systemic treatment with chemotherapy [fluoropyrimidine-based chemotherapy (e.g., 5-fluorouracil, capecitabine), oxaliplatin, irinotecan] AND Erbitux (cetuximab) will be given in combination with Krazati (adagrasib).
Part B Prerequisite	0

#### **ERIVEDGE - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Erivedge (vismodegib) therapy is not considered medically necessary for members with the following concomitant conditions:Members that have experienced disease progression while on Erivedge (vismodegib). Members that are using Erivedge (vismodegib) as neoadjuvant therapy.
Required Medical Information	Advanced Basal Cell Carcinoma. The member has a diagnosis of metastatic basal cell carcinoma OR The member has a diagnosis of locally advanced basal cell carcinoma AND one of the following applies: The member has disease that has recurred following surgery OR the member is not a candidate for surgery AND radiation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	NA
Part B Prerequisite	0

#### **ERLEADA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Erleada (apalutamide).
Required Medical Information	Prostate Cancer (non-metastatic castration resistant): The member has a diagnosis of non-metastatic castration resistant prostate cancer AND the member will use Erleada (apalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchioectomy or GnRH analog). Prostate Cancer (metastatic castration-sensitive): The member has a diagnosis of metastatic castration-sensitive prostate cancer AND the member will use Erleada (apalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchioectomy or GnRH analog).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### erlotinib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pancreatic Cancer: The member has a diagnosis of unresectable, locally advanced or metastatic pancreatic cancer. AND erlotinib is being used in combination with Gemzar (gemcitabine).Non-small cell lung cancer. The member has a diagnosis of metastatic NSCLC AND all of the following apply: The member has known documented activated EGFR mutation (such as E19del in exon 19 or L858R in exon 21). Renal Cell Carcinoma: Diagnosis of relapsed or unresectable stage IV renal cell carcinoma with non clear histology and erlotinib will be used as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### eslicarbazepine - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: Member has a diagnosis of partial-onset (focal) seizures AND Member will not use Aptiom (eslicarbazepine) in combination with oxcarbazepine AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **EULEXIN - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of prostate cancer AND will be using Eulexin (flutamide) alone or in combination therapy with a luteinizing hormone-releasing hormone (LHRH) analog.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### everolimus (antineoplastic) - TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on everolimus.
Required Medical Information	Advanced Renal Cell Carcinoma (RCC). The member has a diagnosis of advanced /metastatic renal cell carcinoma (stage IV) AND the member experienced intolerance on Cabometyx (cabozantinib) as second line therapy [e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome) AND Everolimus is given as monotherapy or being given in combination with Lenvima (lenvatinib). Subependymal Giant Cell Astrocytoma (SEGA) with TSC [Adults and Pediatrics]. The member has a diagnosis of Subependymal Giant Cell Astrocytoma (SEGA) associated with tuberous sclerosis complex AND The member requires therapeutic intervention but is not a candidate for curative surgical resection. Neuroendocrine Tumors: The member has disease that is unresectable, locally advanced or metastatic and one of the following applies: The member has a diagnosis of progressive neuroendocrine tumors of pancreatic origin (PNET) OR The member has a diagnosis of progressive, well differentiated, non-functional neuroendocrine tumors of gastrointestinal or lung.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	Angiomyolipoma and Tuberous Sclerosis Complex (TSC). The member has a diagnosis of renal angiomyolipoma and tuberous sclerosis complex AND Immediate surgery is not required. Metastatic Breast Cancer. The member has a diagnosis of hormone receptor (HR) positive and human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic disease AND the member has previously been treated with endocrine therapy (e.g. letrozole, anastrozole) AND The member will use Everolimus in combination with exemestane or fulvestrant. Tuberous sclerosis complex (TSC)- associated partial onset seizures [Adults and Pediatrics]: The member has diagnosis of TSC- associated partial onset seizures AND Everolimus tablets for oral solution is being used as adjunctive therapy.

#### everolimus (antineoplastic) - TABLET FOR SUSPENSION

Part B	0
Prerequisite	

#### **EXKIVITY - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Exkivity (mobocertinib).
Required Medical Information	Metastatic Non-Small Cell Lung Cancer (NSCLC): The member has locally advanced or metastatic NSCLC AND The NSCLC has documented EGFR exon 20 insertion mutation AND The member has experienced disease progression on platinum based therapy AND Exkivity (mobocertinib) is administered as single agent as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

#### FANAPT - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member must be utilizing Fanapt for treatment of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I Disorder (manic or mixed episode): The member must be utilizing Fanapt for the treatment of bipolar I disorder (manic or mixed episode). The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, of the following: risperidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### FANAPT TITRATION PACK A - TABLET, DOSE PACK

	-
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member must be utilizing Fanapt for treatment of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I Disorder (manic or mixed episode): The member must be utilizing Fanapt for the treatment of bipolar I disorder (manic or mixed episode). The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, of the following: risperidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### FANAPT TITRATION PACK B - TABLET, DOSE PACK

	-
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member must be utilizing Fanapt for treatment of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I Disorder (manic or mixed episode): The member must be utilizing Fanapt for the treatment of bipolar I disorder (manic or mixed episode). The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## FANAPT TITRATION PACK C - TABLET, DOSE PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member must be utilizing Fanapt for treatment of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I Disorder (manic or mixed episode): The member must be utilizing Fanapt for the treatment of bipolar I disorder (manic or mixed episode). The member must have prior therapy or intolerance or contraindication to at least 2 of the following: risperidone, of the following: risperidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# FASENRA PEN - AUTO-INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Severe Asthma with an Eosinophilic Phenotype: The member has a diagnosis of severe asthma AND the member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of greater than or equal to 150 cells/microliter at therapy initiation OR greater than or equal to 300 cells/microliter in the previous 12 months. The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy (e.g. mometasone greater than 400mcg daily, fluticasone greater than 440 mcg daily) in combination with a long acting beta agonist (e.g. formoterol). Eosinophilic Granulomatosis with Polyangiitis (EGPA) - Nucala and Fasenra only: The member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the member has a baseline elevated peripheral blood eosinophil level of greater than 10% of total leukocyte count AND The member has been unable to achieve adequate control of EGPA while on oral corticosteroid therapy (e.g. prednisone, methylprednisolone). Hypereosinophilic Syndrome (HES) - Nucala only: The member has a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophil level of greater than a baseline blood eosinophil level of greater than a baseline blood eosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than or equal to 1000 cells/microliter.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Chronic Rhinosinusitis with Nasal Polyposis - Nucala Only: The member must meet ALL of the following criteria: Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Nucala (mepolizumab) will be used in conjunction with a daily intranasal corticosteroid spray AND member is unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy.
Part B Prerequisite	0

# fentanyl citrate - LOZENGE ON A HANDLE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Treatment of acute or post-operative pain.
Required Medical Information	The member is currently diagnosed with cancer. Fentanyl citrate is required to manage breakthrough cancer pain. The member is currently taking opioid therapy and is opioid tolerant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### FETZIMA - CAPSULE, EXTENDED RELEASE 24HR

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Major depressive disorder: The member must be utilizing Fetzima for treatment of major depressive disorder. For new starts only: The member must have a documentation of prior therapy, intolerance, or contraindication to a serotonin and norepinephrine reuptake inhibitor (SNRI) AND a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) or mirtazapine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# fingolimod - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## FINTEPLA - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Dravet Syndrome: The member has a diagnosis of seizures associated with Dravet Syndrome AND Fintepla (fenfluramine) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member has been unable to achieve seizure control with at least one other drug used for the treatment of Dravet Syndrome (e.g. clobazam, valproic acid, topiramate). Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut syndrome AND Fintepla (fenfluramine) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The member has been unable to achieve seizure control with at least two other drugs used for the treatment of Lennox-Gastaut syndrome (e.g. valproic acid, lamotrigine, rufinamide, topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### FIRDAPSE - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	History of seizures (not to be inferred from pharmacy claims)
Required Medical Information	Lambert-Eaton Myasthenic Syndrome (LEMS). The member has a confirmed diagnosis of Lambert-Eaton Myasthenic Syndrome (LEMS) by a specialist (e.g. neurologist) AND The diagnosis is supported by results from a clinical evaluation (e.g. electromyography or the presence of autoantibodies directed against VGCC {voltagegated calcium channels}).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# FIRMAGON - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	The patient has a diagnosis of advanced prostate cancer or has a high risk of disease recurence.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# FIRMAGON KIT W DILUENT SYRINGE - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	The patient has a diagnosis of advanced prostate cancer or has a high risk of disease recurence.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# FOLOTYN - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on pralatrexate.
Required Medical Information	Peripheral T-cell Lymphoma(PTCL):relapsed or refractory. Pralatrexate is being used to treat relapsed or refractory peripheral T-cell lymphoma (PTCL) (eg peripheral T-cell lymphoma, not otherwise specified: angioimmunoblastic T-cell lymphoma, anaplastic large cell lymphoma or enteropathy-associated T-cell lymphoma.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# FORTEO - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member is postmenopausal with a diagnosis of osteoporosis. The member is at high risk for osteoporotic fracture as evident by one of the following: The member has a history of osteoporotic fracture OR The member has new fractures or significant loss of bone mineral density despite previous treatment contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate). The member is taking sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone). The member is at high risk for osteoporotic fracture as evident by one of the following: The member has a history of osteoporotic fracture OR The member has a history of osteoporotic fracture OR The member has new fractures or significant loss of bone mineral density despite previous treatment, contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate). The member has a diagnosis of primary or hypogonadal osteoporosis, who is at high risk for fracture, defined as history of osteoporotic fracture, or who have multiple risk factors for fracture.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **FOTIVDA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Fotivda (tivozanib).
Required Medical Information	Relapsed or refractory advanced renal cell carcinoma: The member has a diagnosis of relapsed or refractory advanced renal cell carcinoma AND The member has received two prior systemic therapies (e.g., immuno- oncology checkpoint inhibitors, cabozantinib, axitinib) AND Fotivda (tivozanib) is given as a single agent for subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **FRUZAQLA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has had disease progression on Fruzaqla (fruquintinib).
Required Medical Information	Metastatic Colorectal Cancer (mCRC). Member has a diagnosis of metastatic colorectal cancer (mCRC) AND Member has been previously treated with the following: fluoropyrimidine-, oxaliplatin-, and irinotecan- based chemotherapy AND anti-VEGF therapy (e.g., bevacizumab product) AND anti-EGFR therapy [if verified KRAS/NRAS wild-type (normal) and medically appropriate].
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# FYARRO - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has a history of severe hypersensitivity to sirolimus, other rapamycin derivatives, or albumin. Member experiences disease progression on Fyarro (sirolimus protein-bound particles for injectable suspension).
Required Medical Information	Perivascular epithelioid cell tumor. The member had diagnosis of locally advanced unresectable or metastatic perivascular epithelioid cell tumor AND Fyarro (sirolimus protein-bound particles for injectable suspension) will be administered as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### FYCOMPA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: The member has a diagnosis of partial- onset (focal) seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate). Adjunctive treatment of generalized tonic-clonic seizures: The member has a diagnosis of generalized tonic-clonic seizures AND Member will use Fycompa (perampanel) in combination with at least one other drug for controlling seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling generalized tonic-clonic seizures (e.g. lamotrigine, topiramate, carbamazepine, gabapentin, divalproex).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# GAMUNEX-C - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	For Medicare Part D requests, Humana's preferred product is Gamunex- C. Diagnosis of a primary humoral immunodeficiency disorder such as: primary immunoglobulin deficiency syndrome, X-linked immunodeficiency with hyperimmunoglobulin, etc)OR Documented hypogammaglobulinemia (IgG less than 600mg/dl) Idiopathic/Immune Thrombocytopenia Purpura. Diagnosis of Acute ITP with any of the following: Management of acute bleeding due to severe thrombocytopenia (platelets less than 30,000/L), To increase platelet counts prior major surgical procedures, Severe thrombocytopenia (platelets less than 20,000/mcL), at risk for intracerebral hemorrhage. Diagnosis of Chronic ITP and ALL of the following are met:Prior treatment has included corticosteroids, No concurrent illness explaining thrombocytopenia, Platelets persistently at or below 20,000/mcL.Chronic Lymphocytic Leukemia (CLL, B-cell).With either of the following present: Hypogammaglobulinemia (IgG less than 600mg/dL),Recurrent bacterial infections associated with B-cell CLL. Kawasaki Disease. Diagnosed with Kawasaki Syndrome within ten days of onset of disease manifestations or is diagnosed after ten days of disease onset and continues to exhibit manifestations of inflammation or evolving coronary artery disease.IVIG is used in combination with high dose aspirin for the prevention of coronary artery aneurysms.Bone Marrow Transplant (BMT). Member is hypogammaglobulinemia (IgG less than 400mg/dL). Hematopoietic Stem Cell Transplantation (HSCT). Is within first 100 days of allogenic hematopoeietic stem cell transplantation. Is experiencing hypogammaglobulinemia (serum IgG level less than 400 mg/dL). AIDS/HIV. Has any of the following conditions: CD4+ T-cell counts greater than or equal 200/mm3, to prevent maternal transmission of HIV infection, IVIG is used in conjunction with zidovudine to prevent serious bacterial infections in HIV-infected members who have hypogammaglobulinemia (serum IgG less than 400 mg/dL).
Age Restriction	Member is younger than 13 years of age for treatment of AIDS/HIV.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### GAMUNEX-C - VIAL (ML)

Other Criteria

Infections in Low-Birthweight Neonates. Prophylaxis and treatment of infections in high-risk, preterm, low-birth weight members. Diagnosed with staphylococcal / streptococcal toxic shock syndrome. Infection is refractory to several hours of aggressive therapy, an undrainable focus is present, or has persistent oliguria with pulmonary edema. Diagnosed with autoimmune neutropenia and G-CSF therapy is not appropriate. Autoimmune Hemolytic Anemia. Is refractory to corticosteroid therapy and splenectomy, or for those whom corticosteroid therapy and splenectomy is contraindicated. Myasthenia Gravis. Is experiencing acute myasthenic crisis with decompensation. Other treatments have been unsuccessful (e.g., corticosteroids, azathioprine, cyclosporine, and cyclophosphamide). Guillain-Barre Syndrome. Is severely affected by the disease and requires an aid to walk. Diagnosed with biopsy-proven polymyositis OR dermatomyositis and has failed treatment with corticosteroids and azathioprine or methotrexate. Diagnosed with multifocal motor neuropathy confirmed by electrophysiologic studies. Diagnosed with relapsing-remitting multiple sclerosis and has failed conventional therapy (Betaseron, Avonex, etc.).Parvovirus B19 Infection, chronic. Chronic Parvovirus B19 infection with severe anemia associated with bone marrow suppression. Chronic Inflammatory Demyelinating Polyneuropathies. Not responded to corticosteroid treatment. One of the following criteria are met: Electrodiagnostic evidence of demyelinating neuropathy in at least two limbs, OR There is muscle weakness and diagnostic testing was conducted in accordance with AAN diagnostic criteria. Diagnosis of Lambart-Eaton myasthenic syndrome confirmed by electrophysiologic studies. Has not responded to diaminopyridine, azathioprine, corticosteroids, or anticholinesterases. Neonate is diagnosed with isoimmune hemolytic disease. Allosensitized Solid Organ Transplantation. Allosensitized members who are awaiting solid organ transplant. Multiple Myeloma. Has life-threatening infections OR the member is experiencing hypogammaglobulinemia (IgG less than or equal to 400mg/dL). Autoimmune Blistering Diseases. Biopsy-proven diagnosis of an autoimmune blistering disease such as epidermolysis bullosa acquisista, etc. Has tried and failed conventional therapy or has rapidly progressive disease in which a clinical response could not be affected quickly enough using conventional agents. Stiff-Person Syndrome. Other interventions (diazepam) have been unsuccessful. Systemic Lupus Erythematosus. Active/chronic SLE that is refractory to corticosteroid therapy or in members with hemolytic anemia/ thrombocytopenia. Prevention of Bacterial / Viral Infections in Nonprimary Immunodeficiency Members. Experiencing iatrogenically induced or disease associated immunosuppression. Or diagnosed with hematologic malignancy, extensive burns, or collagen-vascular disease. BvsD Coverage Determination may also be required. 0 Prerequisite

Part B

#### **GAVRETO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on RET inhibitors (e.g., pralsetinib, selpercatinib).
Required Medical Information	Non-small cell lung cancer: The member has a diagnosis of metastatic non-small lung cancer AND the disease is documented as RET fusion positive AND Gavreto (pralsetinib) is being used as monotherapy. Thyroid cancer: The member has a diagnosis of metastatic or advanced thyroid cancer AND The disease is documented RET fusion positive AND The disease is radioactive iodine refractory AND Gavreto (pralsetinib) is being used as monotherapy for systemic therapy.
Age Restriction	Thyroid Cancer: The member is 12 years of age and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

## GAZYVA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Gazyva (obinutuzumab). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Required Medical Information	Chronic Lymphocytic Leukemia: The member must have a diagnosis of chronic lymphocytic leukemia AND The member is using Gazyva (obinutuzumab) in combination with Chlorambucil OR the member is using Gazyva (obinutuzumab) in combination with bendamustine OR the member is using Gazyva (obinutuzumab) in combination with Venclexta (venetoclax) OR the member is using Gazyva (obinutuzumab) as monotherapy. Follicular Lymphoma: The member has a diagnosis of follicular lymphoma AND One of the following sets of criteria apply: The member will be using Gazyva (obinutuzumab) for first line therapy OR The member has relapsed after, or is refractory to, a rituximab-containing regimen (defined as progression on or within 6 months of prior rituximab product therapy) AND The member will initially be using Gazyva (obinutuzumab) in combination with chemotherapy (e.g. CHOP, CVP, bendamustine) (after 6-8 cycles Gazyva (obinutuzumab) may be continued as monotherapy per reauthorization criteria below). Follicular LymphomaReauthorization Criteria: The member has achieved stable disease, complete response, or partial response after therapy with Gazyva (obinutuzumab) in combination with chemotherapy (e.g. CHOP, CVP, bendamustine).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# gefitinib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) AND the following applies: The member has a documented epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation AND The member is using Iressa (gefitinib) as monotherapy (without concomitant chemotherapy).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

#### **GILOTRIF - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND the following apply: The member has a documented non-resistant epidermal growth factor receptor (EGFR) mutation (sensitizing EGFR mutation e.g., exon 19 deletion, L861Q, S768I, G719X, L858R) AND The member is using Gilotrif (afatinib) as monotherapy (without concomitant chemotherapy) OR squamous cell histology after disease progression on platinum containing chemotherapy and is using Gilotrif (afatinib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA
Part B Prerequisite	0

# glatiramer - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# glatopa - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### **GLEOSTINE - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Gleostine (lomustine).
Required Medical Information	Brain Tumors. The member has a diagnosis of primary or metastastic brain tumor AND one of the following applies: the member will use Gleostine (lomustine) after appropriate surgical and/or radiotherapeutic procedures OR the member has recurrent or progressive disease. Hodgkin Lymphoma. The member has a diagnosis of Hodgkin Lymphoma AND the member has disease progression following initial chemotherapy AND the member will use Gleostine (lomustine) as a component of combination chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **GOMEKLI - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Neurofibromatosis type 1 (NF1): The member has symptomatic plexiform neurofibromas (PN) [neurofibromatosis type 1 (NF1)] AND The disease is not amenable to complete resection.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# HAEGARDA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hereditary Angioedema (HAE) Prophylaxis: The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2. The member must have documentation of: Evidence of C4 level consistent with diagnosis of HAE Type 1 or 2 AND C1 inhibitor (C1INH) antigenic level consistent with diagnosis of HAE Type 1 or 2 OR C1INH functional level consistent with diagnosis of HAE Type 1 or 2 OR Known HAE-causing C1INH mutation AND The member has a history of recurrent angioedema in the absence of concomitant urticaria AND There are no concomitant or recent use of medications known to cause angioedema (e.g. ACEIs, ARBs) AND Other potential causes of angioedema have been ruled out or considered. The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). Must provide lab report or medical record documentation which include lab values as required by policy. Lab values must include C1q level that is consistent with the diagnosis of HAE. Note: according to the US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema, C1q level is useful to help distinguish between HAE-C1INH and acquired C1INH deficiency. C1q levels are decreased in 80% of acquired C1INH deficiency and rarely low in HAE-C1INH. The member must be using Haegarda for prophylaxis to prevent attacks of HAE.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# HUMIRA - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

# HUMIRA - SYRINGE KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

# HUMIRA PEN - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

# HUMIRA PEN - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

# HUMIRA PEN CROHNS-UC-HS START - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

# HUMIRA PEN CROHNS-UC-HS START - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

# HUMIRA(CF) - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

# HUMIRA(CF) - SYRINGE KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## HUMIRA(CF) PEDI CROHNS STARTER - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEDI CROHNS STARTER - SYRINGE KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## HUMIRA(CF) PEN - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## HUMIRA(CF) PEN CROHNS-UC-HS - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN CROHNS-UC-HS - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## HUMIRA(CF) PEN PEDIATRIC UC - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

# HUMIRA(CF) PEN PEDIATRIC UC - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non-infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## HUMIRA(CF) PEN PSOR-UV-ADOL HS - PEN INJECTOR KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ankylosing Spondylitis. Diagnosis of active ankylosing spondylitis. Member has had prior therapy, contraindication, or intolerance with a non-steroidal anti-inflammatory drug (NSAIDs) (e.g. ibuprofen, meloxicam, naproxen). Mild-Moderate Active Psoriatic Arthritis. Diagnosis of mild-moderately active psoriatic arthritis. Severe Active Psoriatic Arthritis: Diagnosis of severely active psoriatic arthritis. Rheumatoid Arthritis. Diagnosis of moderately to severely active rheumatoid arthritis. Member has had prior therapy with or intolerance to a single DMARD (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide) or contraindication with all DMARDs. Polyarticular Juvenile Idiopathic Arthritis. Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis. Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide). Moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe Chronic Plaque Psoriasis. Diagnosis of moderate to severe chronic plaque psoriasis. The member has had prior therapy with or intolerance to conventional therapy including one or more oral systemic treatments (e.g., methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Oral Ulcers Associated with Behcets Disease: The member has a diagnosis of Behcets disease AND The member will be using for the treatment of oral ulcers AND has had previous treatment with, contraindication, or intolerance with two of the following: topical corticosteroid therapy (e.g. triamcinolone oral paste), azathioprine, colchicine, cyclosporine.
Age Restriction	Must be 18 years of age for Rheumatoid Arthritis, Moderate to severe Chronic Plaque Psoriasis, Psoriatic Arthritis, Ankylosing Spondylitis, Oral Ulcers Associated with Behcets Disease. Must be two years of age or older for moderately to severely active polyarticular juvenile idiopathic arthritis and Uveitis. Must be 6 years or older for Crohns Disease. Must be 5 years of age or older for Ulcerative Colitis. Must be 12 years of age or older for Hidradenitis Suppurativa.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HUMIRA(CF) PEN PSOR-UV-ADOL HS - PEN INJECTOR KIT (EA)

Other Criteria	Ulcerative colitis: Member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member must have moderately to severely active Crohn's disease. Hidradenitis Suppurativa: The member must have a diagnosis of moderate to severe Hidradenitis Suppurativa. Uveitis: The member must have a diagnosis of non- infectious, intermediate, posterior, or pan-uveitis. The member has had prior therapy, contraindication, or intolerance with one of the following: an intravitreal steroid (e.g. triamcinolone, dexamethasone) OR a systemic corticosteroid (e.g. prednisone, methylprednisolone) OR an anti-metabolite (e.g. methotrexate, mycophenolate) OR a calcineurin inhibitor (e.g. cyclosporine).
Part B Prerequisite	0

## HYFTOR - GEL (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Facial Angiofibroma: the member must meet all of the following criteria: diagnosis of tuberous sclerosis complex (TSC), experiencing greater than or equal to three facial angiofibromas, and is not receiving systemic mTOR inhibitor therapy (e.g. everolimus).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## ibandronate - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Postmenopausal Osteoporosis: The member is a postmenopausal with a diagnosis of osteoporosis or at high risk for osteoporosis. The member has new fractures or significant loss of bone mineral density despite previous treatment contraindication or intolerance to another oral OR intravenous bisphosphonate (e.g. alendronate, pamidronate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year
Other Criteria	
Part B Prerequisite	0

#### **IBRANCE - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on CDK 4/6 inhibitor (e.g., ribociclib, abemaciclib).
Required Medical Information	Metastatic Breast Cancer - Combination with Aromatase Inhibitor: The member has a diagnosis of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND The member will be using Ibrance (palbociclib) in combination with an aromatase inhibitor (e.g., letrozole) as initial endocrine-based therapy for their metastatic or recurrent disease. Metastatic Breast Cancer - Combination with Fluvestrant: The member has a diagnosis of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND The member will be using Ibrance (palbociclib) in combination with fulvestrant after disease progression on or following endocrine based therapy ( e.g. anastrazole) for their recurrent disease or the member will be using Ibrance (palbociclib) in combination with fulvestrant as subsequent therapy after disease progression on or following endocrine based therapy (e.g. anastrazole) for their metastatic disease. Metastatic Breast Cancer - PIK3CA-mutated: The member has a diagnosis of hormone receptor 2 (HER2)-negative breast as a diagnosis of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND The disease is documented as, PIK3CA-mutated, as detected by an FDA-test AND The member has endocrine resistant disease [i.e., disease progression on or after adjuvant endocrine therapy (e.g., anastrozole, tamoxifen)] AND Ibrance (palbociclib) will be given in combination with Itovebi (inavolisib) and fulvestrant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

### **IBTROZI - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Part B Prerequisite	Pending CMS Review

# icatibant - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hereditary Angioedema (HAE): The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2. The member must have documentation of: Evidence of C4 level consistent with diagnosis of HAE Type 1 or 2 AND C1 inhibitor (C1INH) antigenic level consistent with diagnosis of HAE Type 1 or 2 OR C1INH functional level consistent with diagnosis of HAE Type 1 or 2 OR Known HAE-causing C1INH mutation AND The member has a history of recurrent angioedema in the absence of concomitant urticaria AND There are no concomitant or recent use of medications known to cause angioedema (e.g. ACEIs, ARBs) AND Other potential causes of angioedema have been ruled out or considered. The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). Must provide lab report or medical record documentation which include lab values as required by policy. Lab values must include C1q level that is consistent with the diagnosis of HAE. Note: according to the US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema, C1q level is useful to help distinguish between HAE-C1INH and acquired C1INH deficiency. C1q levels are decreased in 80% of acquired C1INH deficiency and rarely low in HAE-C1INH. The member is using icatibant for treatment of acute attacks of HAE.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### **ICLUSIG - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Iclusig (ponatinib).
Required Medical Information	Chronic Myeloid Leukemia (chronic phase): The member has a diagnosis of chronic phase chronic myeloid leukemia (CML) AND one of the following apply: The member has an intolerance, resistance, or contraindication to at least two available tyrosine kinase inhibitors indicated for the treatment of CML OR The member has a documented T315I mutation. Chronic Myeloid Leukemia (accelerated or blast phase): The member has a diagnosis of accelerated or blast phase chronic myeloid leukemia (CML) AND one of the following apply: There are no other kinase inhibitors indicated OR the member has a documented T315I mutation. Acute Lymphoblastic Leukemia: The member has a diagnosis of Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) AND one of the following apply: There are no other kinase inhibitors indicated OR The member has a documented T315I mutation OR Iclusig (ponatinib) will be used in combination with chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **IDHIFA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on or following Idhifa(enasidenib).
Required Medical Information	Acute Myeloid Leukemia, Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member has a documented IDH2 mutation AND One of the following applies: The member will be using Idhifa (enasidenib) as monotherapy OR the member will be using Idhifa (enasidenib) as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months). Acute Myeloid Leukemia, Newly diagnosed: The member has a diagnosis of acute myeloid leukemia (AML) AND the member has newly diagnosed disease AND the member is not a candidate for intensive induction therapy due to comorbidities AND the member has a documented IDH2 mutation AND the member will be using Idhifa (enasidenib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	
Part B Prerequisite	0

#### imatinib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Patients that have experienced disease progression while on imatinib.
Required Medical Information	One of the following applies: The member has a diagnosis of Ph+ CML that is newly diagnosed in the chronic phase OR The member has a diagnosis of Ph+ CML that is in accelerated phase or blast crisis OR The member has a diagnosis of Ph+ CML that is in chronic phase after failure of interferon-alpha therapy. Acute lymphoid leukemia (ALL). The member has a diagnosis of Ph+ ALL that is relapsed, refractory, or newly diagnosed and imatinib is being added to consolidation or induction therapy OR the member has a diagnosis of PH+ALL and receiving maintenance therapy. The member has a diagnosis of Dermatofibrosacrome protuberans (DFSP) that is adjuvant (positive surgical margins following excision) unresectable, recurrent, and/or metastatic. The member has a diagnosis of chronic eosinophilic leukemia or hypereosinophilic syndrome. The member has a diagnosis of MDS or chronic MPD that is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangement.(ex. Chronic myelomonocyte leukemia, atypical chronic myeloid leukemia, juvenile myelomonocyte leukemia).The member has a diagnosis of aggressive systemic mastocytosis. The member has a diagnosis of unresectable melanoma with activating mutation of C-kit. Imatinib will be used as single agent in subsequent therapy.
Age Restriction	[Pediatric] Chronic myeloid leukemia (CML) - The member is at least one year of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Pediatric indications: The patient has a diagnosis of Philadelphia chromosome positive (Ph+) CML that is newly diagnosed in chronic phase OR The patient has a diagnosis of Ph+ CML that is in chronic phase with disease recurrence after stem cell transplant OR The patient has a diagnosis of Ph+ CML that is in chronic phase after failure of interferon-alpha therapy.Acute Lymphoid Luekemia (ALL). The member is newly diagnosed with Ph+ ALL AND the member will be using imatinib in combination with chemotherapy.
Part B Prerequisite	0

## IMBRUVICA - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Imbruvica (ibrutinib).
Required Medical Information	Mantle Cell Lymphoma: The member has a diagnosis of Mantle Cell Lymphoma (MCL) AND The member has received at least one prior therapy for the treatment of MCL AND The member is using Imbruvica (ibrutinib) as monotherapy. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL). Waldenstroms Macroglobulinemia: The member has a diagnosis of Waldenstroms macroglobulinemia AND The member is using Imbruvica (ibrutinib) as monotherapy or in combination with a rituximab product. Marginal Zone Lymphoma: The member has a diagnosis of marginal zone lymphoma AND The member is using Imbruvica (ibrutinib) as second line or subsequent for refractory or progressive disease AND The member is using Imbruvica (ibrutinib) as monotherapy. Chronic Graft Versus Host Disease (adult): The member has a diagnosis of chronic graft versus host disease (cGVHD) AND The member has been unable to achieve treatment goals with at least one prior line of systemic therapy (e.g. corticosteroids). Chronic Graft Versus Host Disease (pediatric): The member has a diagnosis of chronic graft versus host disease (cGVHD) AND The member has been unable to achieve treatment goals with at least one prior line of systemic therapy (e.g. corticosteroids).
Age Restriction	pediatric cGVHD: Member age is 1 year or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# IMDELLTRA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on Imdelltra (tarlatamab-dlle).
Required Medical Information	Small Cell Lung Cancer (SCLC): The member has a diagnosis of extensive-stage small cell lung cancer (ES-SCLC) AND the member had progression on or after treatment with platinum-based chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# IMFINZI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	All indications except Bladder Cancer: Disease progression while on or following anti-PD-1/PD-L1 therapy [e.g., Opdivo (nivolumab), Keytruda (pembrolizumab), Tecentriq (atezolizumab), Imfinzi (durvalumab)]. For unresectable stage III NSCLC, member has not exceeded a maximum of twelve (12) months of therapy. For perioperative NSCLC, for adjuvant treatment, member has not exceeded a maximum of 12 cycles after surgery.
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC) (unresectable): Member has diagnosis of unresectable stage III non-small cell lung cancer (NSCLC) AND Imfinzi (durvalumab) will be used as consolidation therapy after completion of concurrent platinum containing chemotherapy and radiation AND Member has not experienced progression of disease after at least two cycles of chemotherapy and radiation AND Imfinzi (durvalumab) will be used as monotherapy OR Member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND Member has no documented EGFR or ALK genomic tumor aberrations AND Member will be using Imfinzi in combination with Imjudo and platinum-based chemotherapy as first-line therapy only. Small Cell Lung Cancer: The member has a diagnosis of extensive-stage small cell lung cancer AND Imfinzi will be given in combination with etoposide and carboplatin as first line therapy followed by maintenance therapy with Imfinzi as a single agent. Biliary Tract Cancer: the member has a diagnosis of locally advanced or metastatic biliary tract cancer AND the member will be using Imfinzi (durvalumab) in combination with gemcitabine and cisplatin. Hepatocellular Carcinoma: The member has a diagnosis of locally advanced unresectable and/or metastatic hepatocellular carcinoma AND The member will be using Imfinzi in combination with Imjudo as first-line therapy only. Endometrial cancer: The member has a diagnosis of primary advanced or recurrent endometrial cancer AND the disease is mismatch repair deficient (dMMR) AND Imfinzi (durvalumab) will be used in combination with carboplatin and paclitaxel followed by Imfinzi (durvalumab) as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	6 months Duration.

# IMFINZI - VIAL (ML)

Other Criteria	Non-small cell lung cancer (perioperative): The member has a diagnosis of non-small cell lung cancer AND The disease is resectable (tumors greater than 4 cm and/or node positive) AND The disease does not have known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements AND Imfinzi (durvalumab) will be used in combination with chemotherapy as neoadjuvant treatment followed by Imfinzi (durvalumab) as monotherapy as adjuvant treatment after surgery. Small Cell Lung Cancer (Limited stage): The member has a diagnosis of limited-stage small cell lung cancer AND The member's disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy AND Imfinzi (durvalumab) will be given as monotherapy. Bladder Cancer: The member has a diagnosis of muscle invasive bladder cancer (MIBC) AND The member will be using Imfinzi (durvalumab) in combination with gemcitabine and cisplatin as neoadjuvant treatment, followed by a single agent Imfinzi (durvalumab) as adjuvant treatment following radical cystectomy.
Part B Prerequisite	0

# IMJUDO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression on Imjudo (tremelimumab-actl)
Required Medical Information	Hepatocellular carcinoma (HCC): The member has diagnosis of unresectable hepatocellular carcinoma AND The member will be given Imjudo (tremelimumab-actl) in combination with Imfinzi (durvalumab). Non-small cell lung cancer (NSCLC): The member has a diagnosis of metastatic, advanced, recurrent non-small cell lung cancer AND NSCLC does not express sensitizing genomic tumor aberrations (e.g., EGFR, ALK) AND The member will be given Imjudo (tremelimumab-actl) in combination with Imfinzi (durvalumab) and platinum based chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

## IMKELDI - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Patients that have experienced disease progression while on imatinib.
Required Medical Information	One of the following applies: The member has a diagnosis of Ph+ CML that is newly diagnosed in the chronic phase OR The member has a diagnosis of Ph+ CML that is in accelerated phase or blast crisis OR The member has a diagnosis of Ph+ CML that is in chronic phase after failure of interferon-alpha therapy. Acute lymphoid leukemia (ALL). The member has a diagnosis of Ph+ ALL that is relapsed, refractory, or newly diagnosed and imatinib is being added to consolidation or induction therapy OR the member has a diagnosis of PH+ALL and receiving maintenance therapy. The member has a diagnosis of Dermatofibrosacrome protuberans (DFSP) that is adjuvant (positive surgical margins following excision) unresectable, recurrent, and/or metastatic. The member has a diagnosis of chronic eosinophilic leukemia or hypereosinophilic syndrome. The member has a diagnosis of MDS or chronic MPD that is associated with platelet-derived growth factor receptor (PDGFR) gene rearrangement.(ex. Chronic myelomonocyte leukemia). The member has a diagnosis of aggressive systemic mastocytosis. The member has a diagnosis of aggressive systemic mastocytosis. The member has a diagnosis of unresectable melanoma with activating mutation of C-kit. Imatinib will be used as single agent in subsequent therapy.
Age Restriction	[Pediatric] Chronic myeloid leukemia (CML) and [Pediatric] Acute Lymphoid Luekemia (ALL) - The member is at least one year of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	Pediatric indications: The patient has a diagnosis of Philadelphia chromosome positive (Ph+) CML that is newly diagnosed in chronic phase OR The patient has a diagnosis of Ph+ CML that is in chronic phase with disease recurrence after stem cell transplant OR The patient has a diagnosis of Ph+ CML that is in chronic phase after failure of interferon-alpha therapy.Acute Lymphoid Luekemia (ALL). The member is diagnosed with Ph+ ALL AND the member will be using imatinib in combination with chemotherapy. For Imkeldi requests (all indications): Members must have an intolerance or contraindication with generic imatinib.

## IMKELDI - SOLUTION, ORAL

Part B Prerequisite
------------------------

# IMLYGIC - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members who are immunocompromised. Members who are pregnant. Members that have experienced disease progression while on Imlygic (talimogene laherparepvec). Concomitant therapy with anti-PD-1/PD-L1 agents (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]).
Required Medical Information	Unresectable Melanoma: The member must have one of the following melanoma diagnoses:unresectable Stage III with in-transit metastases, unresectable local/satellite recurrence (may also have in-transit metastases), unresectable or distant metastatic disease. The member will receive Imlygic as an intralesional therapy into cutaneous, subcutaneous, or nodal lesions that are visible on the skin, palpable, or detectable by ultrasound guidance.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA
Part B Prerequisite	0

### **INBRIJA - CAPSULE, WITH INHALATION DEVICE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Parkinson's Disease off episodes: The member has a diagnosis of Parkinson's disease AND is currently taking carbidopa/levodopa and will continue taking carbidopa/levodopa with Inbrija (inhaled levodopa) AND is experiencing breakthrough off periods related to their Parkinson's disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# INCRELEX - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The bone epiphyses are closed.
Required Medical Information	Member has a diagnosis of GH gene deletion with development of neutralizing antibodies to GH OR The patient has a diagnosis of severe primary IGF-1 deficiency defined by:height standard deviation score below or equal -3.0 and basal IGF-1 standard deviation score below or equal -3.0 and normal or elevated growth hormone.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### INLYTA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Inlyta (axitinib).
Required Medical Information	Renal Cell Carcinoma: The member has a diagnosis of advanced renal cell carcinoma AND Inlyta will be given as one of the following: monotherapy AND the member has a medical reason as to why Cabometyx (cabozantinib) can not be initiated or continued OR in combination with Keytruda or Bavencio as first-line therapy. Advanced Thyroid Carcinoma: The member has a diagnosis of advanced/metastatic follicular carcinoma, Hurthle cell carcinoma, or papillary carcinoma and clinical trials are not available or appropriate AND The member has disease that is not responsive to radio-iodine treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### **INQOVI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression on hypomethylators (e.g. azacitidine, decitabine).
Required Medical Information	Myelodysplastic Syndromes - Chronic Myelomonocytic Leukemia: The member has a diagnosis of myelodysplastic syndromes (MDS), including previously treated and untreated, de novo or secondary MDS OR chronic myelomonocytic leukemia (CMML) AND the member will be using Inqovi (decitabine and cedazuridine) as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA
Part B Prerequisite	0

#### **INREBIC - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Inrebic (fedratinib).
Required Medical Information	Myelofibrosis: The member has a diagnosis of primary myelofibrosis or secondary myelofibrosis (i.e. post-polycythemia vera or post-essential thrombocythemia) AND The member has one of the following risk categories, as defined by accepted risk stratification tools for myelofibrosis (e.g. International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or DIPSS- PLUS): Intermediate-2 risk disease OR High-risk disease AND the member will be using Inrebic (fedratinib) as monotherapy AND The member has a medical reason as to why Jakafi (ruxolitinib) cannot be used.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

# ISTODAX - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on romidepsin.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). Istodax (romidepsin) is being used to treat cutaneous T-cell lymphoma AND one of the following applies: the member will be using Istodax (romidepsin) as primary biologic systemic therapy OR the member has received at least one prior therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **ITOVEBI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on a PIK3CA inhibitor (e.g., alpelisib).
Required Medical Information	Metastatic Breast Cancer - PIK3CA-mutated: The member has a diagnosis of advanced or metastatic hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative breast cancer AND The disease is documented as PIK3CA-mutated, as detected by an FDA-test AND The member has endocrine resistant disease [i.e., disease progression on or after adjuvant endocrine therapy (e.g., anastrozole, tamoxifen)] AND Itovebi (inavolisib) will be given in combination with Ibrance (palbociclib) and fulvestrant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **IWILFIN - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has had prior progression on Iwilfin (eflornithine). Member has been on therapy for more than two years.
Required Medical Information	High-Risk Neuroblastoma (HRNB): Member has diagnosis of high-risk neuroblastoma AND Member has had at least a partial response (or better) to prior multiagent, multimodality therapy including anti-GD2 immunotherapy (e.g., dinutuximab).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## IXEMPRA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced severe (CTC grade 3/4) hypersensitivity reaction to medications formulated with Cremophor EL or its derivatives (e.g. polyoxyethylated castor oil). Ixempra (ixabepilone) should be discontinued after disease progression.
Required Medical Information	Breast Cancer: The member has a diagnosis of locally advanced or metastatic breast cancer AND one of the following: When used as monotherapy: the member has disease that is refractory or resistant to an anthracycline (e.g. Doxorubicin), a taxane (e.g. paclitaxel) and Xeloda (capecitabine) OR When used in conjunction with Xeloda (capecitabine) or 5-FU/fluorouracil: the member has disease that is refractory or resistant to both an anthracycline (e.g. Doxorubicin) and a taxane (e.g. paclitaxel) (or further anthracycline therapy is contraindicated).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### JAKAFI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Jakafi (ruxolitinib).
Required Medical Information	Myelofibrosis. The member has a documented diagnosis of primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis AND The member has one of the following risk categories, as defined by International Prognostic Scoring System (IPSS): Symptomatic low risk disease OR Symptomatic intermediate-1 risk disease OR Intermediate-2 risk disease OR High risk disease. The member will be using Jakafi (ruxolitinib) as monotherapy (excludes medically necessary supportive agents). Polycythemia Vera: The member has a diagnosis of polycythemia vera AND The member has not achieved treatment goals, has an intolerance, or contraindication to hydroxyurea. Acute Graft Versus Host Disease: The member has a diagnosis of steroid-refractory acute graft versus host disease. Chronic Graft Versus Host Disease (cGVHD): The member has a diagnosis of chronic graft-versus-host disease (cGVHD) AND the member has been unable to achieve treatment goals with at least one prior line of systemic therapy (e.g., corticosteroids).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### **JAYPIRCA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Mantle cell lymphoma: The member has a diagnosis of mantle cell lymphoma AND the member has relasped or refractory disease AND the member has received at least two prior lines of systemic therapy, including a BTK inhibitor AND the member will be using Jaypirca (pirtobrutinib) as monotherapy. Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): The member has a diagnosis of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) AND the member has received at least 2 prior lines of therapy, including BTK inhibitor and a BCL-2 inhibitor AND the member will be using Jaypirca (pirtobrutinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# JEMPERLI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g.,nivolumab, pembrolizumab).
Required Medical Information	Endometrial cancer (2nd line or beyond): The member has diagnosis of recurrent or advanced endometrial cancer AND The member has documented dMMR endometrial cancer AND The member has progressed on prior platinum containing regimen AND Jemperli (dostarlimab-gxly) is administered as monotherapy as subsequent therapy. Solid tumors (dMMR): The member has a diagnosis of unresectable or metastatic documented mismatch repair deficient (d-MMR) solid tumors AND the member has disease that has progressed on prior therapy with no alternative treatments AND Jemperli (dostarlimab-gxly) is administered as monotherapy. Endometrial cancer (frontline therapy): The member has diagnosis of primary advanced or recurrent endometrial cancer AND Jemperli (dostarlimab-gxly) will be used in combination with carboplatin and paclitaxel, followed by maintenance therapy as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration. Endometrial cancer (frontline therapy) only: Plan Year Duration.
Other Criteria	
Part B Prerequisite	0

### JEVTANA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Jevtana should not be administered to patients with neutrophils less than or equal to 1,500/mm3. Jevtana should not be given to patients with hepatic impairment (total bilirubin greater than 3 x ULN. Concomitant use with abiraterone acetatate, Yonsa, or Xtandi.
Required Medical Information	Hormone-Refractory Metastatic Prostate Cancer. The member must have a diagnosis of hormone-refractory metastatic prostate cancer. The member must have previously been treated with a docetaxol-containing treatment regimen. The member must be taking Jevtana in combination with concurrent corticosteroid (e.g., dexamethasone, prednisone).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

### JYLAMVO - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute Lymphoblastic Leukemia (ALL): The member has a diagnosis of acute lymphoblastic leukemia AND The member will be using Jylamvo (methotrexate) as part of combination chemotherapy maintenance regimen AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. Mycosis Fungoides: The member has a diagnosis of mycosis fungoides (cutaneous T-cell lymphoma) AND The member will be using Jylamvo (methotrexate) as a single agent or as part of combination chemotherapy regimen AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. Non- Hodgkin lymphomas: The member has a diagnosis of non-Hodgkin lymphoma AND The member will be using Jylamvo (methotrexate) as part of a metronomic combination chemotherapy regimen AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. Rheumatoid Arthritis: The member has a diagnosis of Rheumatoid Arthritis AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. Psoriasis: The member has a diagnosis of severe psoriasis AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. Psoriasis: The member has a diagnosis of severe psoriasis AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. Polyarticular Juvenile Idiopathic Arthritis: The member has a diagnosis of polyarticular juvenile Idiopathic arthritis AND The member has had previous treatment, intolerance or documented difficulty swallowing generic methotrexate tablets. B vs D coverage determination may also be required.
Age Restriction	Mycosis Fungoides, Non-Hodgkin lymphomas, Rheumatoid Arthritis, and Psoriasis: The member must be 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# KADCYLA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Kadcyla (ado-trastuzumab emtansine. Use in the adjuvant setting. Members on concomitant trastuzumab product, Tykerb (lapatinib), or Perjeta (pertuzumab).
Required Medical Information	Metastatic Breast Cancer. The member has a diagnosis of metastatic breast cancer and HER2 (human epidermal growth factor receptor2) positive disease (e.g., defined as IHC 3+ or IHC 2+/ISH positive) AND the member is using Kadcyla (ado-trastuzumab emtansine) as monotherapy AND the member has received prior therapy with a trastuzumab product and a taxane (eg. paclitaxel, docetaxel), separately or in combination and one of the following applies: Received prior treatment for metastatic disease. Recurrence occurred during or within six months of completing adjuvant therapy. Early Breast cancer: The member has a diagnosis of early HER 2 positive breast (e.g., defined as IHC 3+ or IHC 2+/ISH positive) AND the member has received neoadjuvant taxane (e.g. paclitaxel) and trastuzumab containing regimen AND the member is receiving Kadcyla (ado-trastuzumab emtansine) as adjuvant treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **KALYDECO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis: The member must meet ALL of the following criteria: Diagnosis of Cystic Fibrosis AND Prior lab testing with documentation of a mutation in the CFTR gene that is responsive to therapy based on clinical literature and/or in vitro assay data.
Age Restriction	
Prescriber Restriction	The member is being treated by or in consultation with a specialist (e.g. pulmonologist).
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# KANJINTI - VIAL (EA)

	j
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	For Herceptin (trastuzumab), Ogivri, Herzuma or Ontruzant requests: member must have an intolerance or contraindication Trazimera (trastuzumab-qyyp) OR Kanjinti (trastuzumab-anns) and meets below criteria: Breast Cancer: The member has a diagnosis of breast cancer and HER2 (human epidermal growth factor receptor2) positive disease (e.g., defined as IHC 3+ or IHC2+/ISH positive). Gastric Cancer: The member has a diagnosis of advanced, gastric cancer or gastroesophageal adenocarcinoma and HER2 positive disease (e.g., defined as IHC 3+ or IHC2+/ISH positive) AND trastuzumab is being used in combination with cisplatin and fluorouracil or capecitabine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **KERENDIA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic kidney disease associated with type 2 diabetes: The member has a diagnosis of chronic kidney disease (CKD) associated with type 2 diabetes (T2D) AND The member is currently receiving, unless contraindicated or intolerant, the maximally tolerated dose of: Either an angiotensin-converting enzyme inhibitor (e.g. Lisinopril) OR an angiotensin receptor blocker (e.g. losartan).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### KESIMPTA PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### ketoconazole - TABLET

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Systemic Fungal Infection: member has a diagnosis of a systemic fungal infection (i.e., blastomycosis, coccidioidomycosis, histoplasmosis, paracoccidioidomycosis, chromomycosis). Prophylaxis - Transplanted Organ Rejection: member has a transplanted organ AND member will concurrently receive immunuosuppresant therapy with cyclosporine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# KEYTRUDA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following prior anti-PD-1/PD-L1 therapy (e.g., nivolumab, atezolizumab). Member requiring urgent cytoreductive therapy (applicable to PMBCL only). Member not to exceed one year of total adjuvant treatment (applicable to melanoma, NSCLC, and renal cell carcinoma only).
Required Medical Information	Melanoma: unresectable or metastatic melanoma OR melanoma OR stage IIB, IIC, or III melanoma AND as monotherapy for adjuvant treatment after complete resection with involvement of lymph node(s). NSCLC-1st Line: metastatic NSCLC AND 1 of the following applies: disease with PD-L1 expression [TPS greater than or equal to 1%] with no EGFR or ALK genomic tumor aberrations and as 1st line AND tumor expresses PD-L1 as determined by an FDA-approved test AND used as monotherapy OR nonsquamous histology with no EGFR or ALK genomic tumor aberrations and as 1st line AND tumor expresses PD-L1 as determined by the pemetrexed and carboplatin or cisplatin as 1st line therapy followed by Keytruda maintenance in combo with pemetrexed OR squamous histology and used in combo with carboplatin and paclitaxel or Abraxane as 1st line followed by Keytruda maintenance oR stage III NSCLC and not candidate for surgical resection or definitive chemoradiation AND PD-L1 expression with no EGFR or ALK genomic tumor aberrations and as 1st line AND Tumor expresses PD-L1 as determined by an FDA-approved test AND as monotherapy. NSCLC-Subsequent: metastatic NSCLC AND progression on or following chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND Tumor expresses PD-L1 as determined by an monotherapy. Head-Neck Cancer: recurrent or metastatic non-nasopharyngeal head and neck squamous cell carcinoma AND 1 of following: disease progression on platinum-containing chemo and as monotherapy OR in combo with platinum and 5-FU for 1st line treatment OR monotherapy in 1st line and disease expresses CPS score greater than or equal to 1 as detected by an FDA-approved test. Hodgkin's Lymphoma-Peds: monotherapy and 1 of following: Refractory disease OR Relapsed after 2 or more lines of prior therapy. CSCC: recurrent or metastatic CSCC AND disease is not amenable to curative surgery or radiation AND used as a monotherapy.
Age Restriction	Stage IIB, IIC, or III melanoma - member is 12 years of age or older.
Prescriber Restriction	Licensed Practitioner

### KEYTRUDA - VIAL (ML)

Coverage Duration	NSCLC (Neoadjuvant therapy): 3 months duration. All other indications: 6 months duration.
Other Criteria	MSI-High/d-MMR Solid tumors: unresectable or metastatic documented microsatellite instability-high or mismatch repair deficient solid tumors (excluding pediatric patients with MSI-H central nervous system cancers) AND 1 of the following: disease that progressed on prior therapy with no alternative treatments and as monotherapy OR colorectal cancer AND 1 of the following: Keytruda as monotherapy and as subsequent therapy after progression on fluoropyrimidine, oxaliplatin, and irinotecan or 1st line as monotherapy in unresectable or metastatic colorectal cancer. Urothelial Cancer: locally advanced or metastatic urothelial cancer AND 1 of the following: initial therapy in members ineligible to receive platinum containing chemo OR as subsequent monotherapy after disease progression within 12 months of neoadjuvant or adjuvant chemo OR in combination with Padcev (enfortumab vedotin-ejfv) in the front-line setting. Cervical Cancer: recurrent or metastatic cervical cancer AND disease progression on or after chemo AND disease expresses CPS score greater than or equal to 1 as determined by an FDA approved test AND as monotherapy OR persistent, recurrent, or metastatic cervical cancer AND and pediatrics]: relapsed or refractory disease after 2 or more prior lines of treatment AND as monotherapy. Merkel cell carcinoma-Adult and pediatrics]: relapsed or refractory disease after 2 or more prior lines of treatment AND as monotherapy. HCC: has prior therapy with a 1st line therapy (e.g., sorafenib) AND as monotherapy. RCC: advanced or metastatic RCC AND in combo with Inlyta or Lenvima as 1st line therapy. Esophageal Cancer: recurrent locally advanced or metastatic or recurrent lending as a single agent. Endometrial cancer: metastatic or recurrent high-grade bladder cancer within 6 months of surgery or radiation AND has experienced disease progression on prior systemic therapy AND as monotherapy. TMC: has proved test AND given as subsequent therapy as a single agent. Endometrial cancer: metastatic or recurrent high-grade bladde

Y0040\_GHHJPMNES\_C

### KEYTRUDA - VIAL (ML)

Part B Prerequisite	0				
------------------------	---	--	--	--	--

# KIMMTRAK - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Kimmtrak (tebentafusp-tebn).
Required Medical Information	Metastatic Uveal Melanoma: the member has a diagnosis of unresectable or metastatic uveal melanoma AND the member has documentation of HLA-A 02:01 positive disease by assay results AND Kimmtrak (tebentafusp-tebn) will be used as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### KISQALI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on CDK 4/6 inhibitor (e.g., palbociclib, abemaciclib). Early Breast Cancer: Member exceeds three years of total Kisqali (ribociclib) based treatment.
Required Medical Information	Breast Cancer-Combination with Aromatase Inhibitors. The member has a diagnosis of advanced or metastatic hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (Her2neu)-negative breast cancer AND the member will be using Kisqali (ribociclib) in combination with an aromatase inhibitor (e.g., letrozole) as first line endocrine therapy. Breast Cancer- Combination with fulvestrant. The member has a diagnosis of advanced or metastatic hormone receptor- positive and human epidermal growth factor receptor 2-negative breast cancer AND the member will be using Kisqali (ribociclib) in combination with fulvestrant. Early Breast Cancer-Combination with Aromatase Inhibitor: The member has a diagnosis of hormone receptor (HR) - positive and human epidermal growth factor receptor 2 (HER2) - negative, stage II or III early breast cancer at high risk of recurrence AND the member will be using Kisqali (ribociclib) in combination with an aromatase inhibitor (e.g., letrozole) as adjuvant treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **KISQALI FEMARA CO-PACK - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on CDK 4/6 inhibitor (e.g., palbociclib, abemaciclib). Early Breast Cancer: Member exceeds three years of total Kisqali (ribociclib) based treatment.
Required Medical Information	Breast Cancer-Combination with Aromatase Inhibitors. The member has a diagnosis of advanced or metastatic hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (Her2neu)-negative breast cancer AND the member will be using Kisqali (ribociclib) in combination with an aromatase inhibitor (e.g., letrozole) as first line endocrine therapy. Breast Cancer- Combination with fulvestrant. The member has a diagnosis of advanced or metastatic hormone receptor- positive and human epidermal growth factor receptor 2-negative breast cancer AND the member will be using Kisqali (ribociclib) in combination with fulvestrant. Early Breast Cancer-Combination with Aromatase Inhibitor: The member has a diagnosis of hormone receptor (HR) - positive and human epidermal growth factor receptor 2 (HER2) - negative, stage II or III early breast cancer at high risk of recurrence AND the member will be using Kisqali (ribociclib) in combination with an aromatase inhibitor (e.g., letrozole) as adjuvant treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

### klayesta - POWDER (GRAM)

DA Critorio	Critoria Dataila
PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

### **KOSELUGO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experienced disease progression on Koselugo (selumetinib)
Required Medical Information	Neurofibromatosis type 1: The member has a diagnosis of neurofibromatosis type 1 which is symptomatic, inoperable plexiform neurofibromas and Koselugo (selumetinib) is given as a monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### KRAZATI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experienced disease progression on KRAS G12C inhibitor (e.g., sotorasib, adagrasib).
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of locally advanced or metastatic NSCLC AND the NSCLC has documented KRAS G12C mutation AND the member has experienced disease progression on one prior therapy AND Krazati (adagrasib) will be given as monotherapy. Colorectal Cancer (CRC): The member has a diagnosis of locally advanced or metastatic colorectal cancer (CRC) AND the CRC has a documented KRAS G12C mutation AND the member has received prior systemic treatment with chemotherapy [fluoropyrimidine- based chemotherapy (e.g., 5-fluorouracil, capecitabine), oxaliplatin, irinotecan] AND Krazati (adagrasib) will be given in combination with Erbitux (cetuximab).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

### KYPROLIS - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Kyprolis (carfilzomib).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of Multiple Myeloma AND The member is using Kyprolis (carfilzomib) as a single agent or in combination with dexamethasone for disease relapse or progressive disease OR the member will be using Kyprolis (carfilzomib) in combination with Pomalyst (pomalidomide) and dexamethasone and the member has received at least two prior therapies, including an immunomodulatory agent (e.g. thalidomide, lenalidomide, pomalidomide) and a proteasome inhibitor (e.g. bortezomib) (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND the member has demonstrated disease progression on or within 60 days of completion of the last therapy OR The member will be using Kyprolis (carfilzomib) in combination with Revlimid (lenalidomide) and dexamethasone or in combination with cyclophosphamide and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) and one of the following applies: Is using as primary therapy OR Using for treatment of disease relapse (disease relapse must be after 6 months following primary chemotherapy with the same regimen) or progressive disease OR the member will be using Kyprolis (carfilzomib) in combination with CD38 inhibitor (e.g., daratumumab product, isatuximab) and dexamethasone and the member has received at least one prior line of therapy (Omission of corticosteroid from regimen is allowed if intolerance/contraindication).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	Waldenstrom's Macroglobulinemia: The member has a diagnosis of Waldenstrom's macroglobulinemia AND Kyprolis (carfilzomib) will be used as a component of CaRD regimen (carfilzomib, rituximab, and dexamethasone) as primary therapy (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) OR for relapsed disease (if CaRD previously used as primary therapy relapse must occur after 24 months).
Part B Prerequisite	0

# lanreotide - SYRINGE (ML)

	-
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Diagnosis of acromegaly. The member has a diagnosis of acromegaly. The member has had an inadequate response to or cannot be treated with traditional therapies including surgury and/or radiation therapy. Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs): The member has a diagnosis of unresectable, well- or moderately- differentiated, locally advanced, or metastatic gastroenteropancreatic neuroendocrine tumors. Carcinoid Syndrome: The member has a diagnosis of carcinoid syndrome with symptoms of flushing and/or diarrhea.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### lapatinib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Tykerb (lapatinib).
Required Medical Information	Breast Cancer. The member has a diagnosis of HER2(human epidermal growth factor receptor2) positive advanced or metastatic breast cancer AND The member had prior therapy, contraindication, or intolerance with an anthracycline (e.g. doxorubicin) and a taxane (e.g. paclitaxel) OR The member has a diagnosis of HER2 positive metastatic breast cancer AND Used as first line treatment in combination with an aromatase inhibitor (Femara (letrozole), Arimidex (anastrozole) or Aromasin (exemestane)) for hormone receptor positive disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 month duration
Other Criteria	
Part B Prerequisite	0

### LAZCLUZE - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND the NSCLC has a documented epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations AND Lazcluze (lazertinib) will be given in combination with Rybrevant (amivantamab) in the first-line setting.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### lenalidomide - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on lenalidomide.
Required Medical Information	Myelodysplastic Syndromes (MDS) with 5Q deletion. The member has a diagnosis of low- or intermediate-1 risk myelodysplastic syndrome (MDS) AND the member has a documented deletion 5q chromosomal abnormality AND the member has one of the following: Symptomatic Anemia (e.g. chronic fatigue, malaise) OR Transfusion-dependent anemia OR Anemia that is not controlled with erythroid stimulating agent. Myelodysplastic Syndromes (MDS) without 5Q deletion (non-5Q deletion). The member has a diagnosis of low- or intermediate-1 risk myelodysplastic syndrome (MDS) AND the member has no documented 5q deletion abnormality AND the member has one of the following: Symptomatic Anemia (e.g. chronic fatigue, malaise) OR Transfusion-dependent anemia OR Anemia that is not controlled with erythroid stimulating agent. Multiple Myeloma. Diagnosis of active Multiple Myeloma or Systemic Light Chain Amyloidosis. Primary induction OR for relapsed/refractory disease, lenalidomide therapy should be utilized in conjunction with dexamethasone if no contraindication. As maintenance therapy in patients with multiple myeloma following autologous hematopoietic stem cell transplantation. Chronic Lymphoid Leukemia. Diagnosis of relapsed or refractory Chronic Lymphocytic Leukemia (CLL).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Hodgkin Lymphoma: The member has a diagnosis of classical Hodgkin lymphoma AND The member has relapsed or refractory disease AND The member will be using for third line or subsequent systemic therapy. Non-Hodgkin Lymphoma: The member has one of the following diagnoses: AIDS-related B-cell lymphoma, diffuse large B-cell lymphoma, mucosa-associated lymphoid tissue (MALT) lymphoma [either gastric or nongastric], marginal zone lymphoma, or mantle cell lymphoma AND The member has relapsed or refractory disease OR The member has a diagnosis of follicular lymphoma AND The member will use as first line therapy or for relapsed or refractory disease.
Part B Prerequisite	0

#### LENVIMA - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Lenvima (lenvatinib).
Required Medical Information	Thyroid Cancer: The member has a diagnosis of locally recurrent or metastatic, progressive differentiated thyroid cancer (i.e. papillary carcinoma, follicular carcinoma or Hurthle cell carcinoma) AND The tumors are not responsive to radio-iodine treatment AND Lenvima (lenvatinib) will be used as monotherapy. Renal Cell Carcinoma. The member has a diagnosis of advanced renal cell carcinoma AND the member is using in combination with Afinitor (everolimus) AND the member has experienced intolerance on Cabometyx (cabozantinib) as second line therapy [e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome). Hepatocelluar Carcinoma: The member has a diagnosis of unresectable carcinoma AND Lenvima (lenvatinib) will be given as a single agent as first line therapy. Endometrial cancer AND The disease is not MSI-H or documented mismatch repair proficient (pMMR) as determined by an FDA-approved test AND The member has experienced disease progression on prior systemic therapy AND Lenvima (levantinib) will be given in combination with Keytruda (pembrolizumab) as subsequent therapy. Renal cell carcinoma- first line therapy: The member has a diagnosis of advanced renal cell carcinoma AND Lenvima (levatinib) will be given in combination with Keytruda (pembrolizumab) as first line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### leuprolide (3 month) - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

### levoleucovorin calcium - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with pernicious anemia or megaloblastic anemia secondary to the lack of vitamin B12.
Required Medical Information	Osteosarcoma: The member is being treated with high dose methotrexate for osteosarcoma. The patient has been treated with leucovorin calcium and has experienced documented side effects either due to lack of leucovorin calcium efficacy OR due to leucovorin calcium formulation necessitating a change in therapy. Impaired methotrexate elimination or inadvertent over dosage of folic acid antagonists. The patient has been treated with methotrexate or other folic acid antagonist and is currently exhibiting signs of toxicity likely due to aforementioned therapy. The patient has been treated with leucovorin calcium and has experienced documented side effects either due to lack of leucovorin calcium efficacy or due to leucovorin calcium formulation necessitating a change in therapy. Advanced Metastatic Colorectal Cancer. The member has advanced metastatic colorectal cancer. The member is receiving palliative treatment with combination chemotherapy with 5-fluorouracil AND The member has been treated with leucovorin calcium and has experienced documented side effects either due to lack of leucovorin calcium and has experienced documented side effects due to leucovorin calcium and has
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# LIBTAYO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on or after prior PD-1/PD-L1 inhibitor (e.g., Keytruda).
Required Medical Information	Cutaneous squamous cell carcinoma. The member has a diagnosis of locally advanced or metastatic cutaneous squamous cell carcinoma (CSCC) AND the disease is not amenable to curative surgery or radiation AND Libtayo (cemiplimab-rwlc) is being used as a monotherapy. Basal cell carcinoma (BCC): The member has locally advanced BCC or metastatic BCC AND the disease has been treated with prior hedgehog pathway inhibitor OR treatment with a hedgehog pathway inhibitor is inappropriate AND Libtayo (cemiplimab-rwlc) is given monotherapy. Non-small cell lung cancer (NSCLC): The member has a diagnosis of NSCLC without tumor aberrations (e.g., EGFR, ALK, ROS-1) AND The disease is locally advanced (not amenable to surgery or definitive chemoradiation) or metastatic AND The tumor expresses documented high PD-L1 expression [Tumor Proportion Score (TPS) greater than or equal to 50%] AND Libtayo (cemiplimab-rwlc) is given as monotherapy OR Libtayo (cemiplimab-rwlc) is given in combination with platinum based chemotherapy as first line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

### lidocaine - ADHESIVE PATCH, MEDICATED

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Post-Herpetic Neuralgia: The member must have a diagnosis of post- herpetic neuralgia. Diabetic Neuropathy: The member must have a diagnosis of diabetic neuropathy. Neuropathic cancer pain. The member must have a diagnosis of neuropathic cancer pain. Chronic Back Pain: The member must have a diagnosis of chronic back pain. Pain associated with hip or knee osteoarthritis: the member must have a diagnosis of pain associated with hip or knee osteoarthritis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### liraglutide - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member is using for weight loss.
Required Medical Information	Diabetes Mellitus. The member has a diagnosis of type 2 diabetes mellitus AND Previous treatment with, contraindication to, or intolerance with TWO of the following: Mounjaro, Ozempic, Rybelsus, or Trulicity. Previous treatment requirement does not apply to liraglutide requests for pediatric members (10 to 17 years of age).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### LIVTENCITY - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must have a diagnosis of cytomegalovirus (CMV) post- transplant AND The member must be refractory to treatment with ganciclovir, valganciclovir, cidofovir or foscarnet.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### LONSURF - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Lonsurf.
Required Medical Information	Metastatic Colorectal Cancer: The member has a diagnosis of metastatic colorectal cancer AND The member is using Lonsurf as monotherapy or in combination with bevacizumab product AND The member has experienced disease progression, intolerance, or contraindication with the following therapies: fluoropyrimidine-based chemotherapy (e.g., 5-fluorouracil, capecitabine), oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, and if appropriate, an anti-VEGF therapy (e.g. bevacizumab product) AND If the member is RAS wild-type: the member has experienced disease progression, intolerance, or contraindication with anti-EGFR therapy (e.g. cetuximab or panitumumab). Gastric cancer. The member has recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma AND The member has experienced disease progression on or after two lines of therapy including fluoropyrimidine (e.g., 5-fluorouracil), platinum (e.g., cisplatin), either taxane (e.g., paclitaxel) or irinotecan and if appropriate, HER2/neu-targeted therapy (e.g., trastuzumab) AND Lonsurf will be given subsequent therapy as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	
Part B Prerequisite	0

# LOQTORZI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on or after prior PD-1/PD-L1 inhibitor (e.g., Keytruda).
Required Medical Information	Nasopharyngeal carcinoma (NPC): The member has a diagnosis of metastatic or recurrent, locally advanced NPC AND One of the following applies: Loqtorzi (toripalimab-tpzi) will be used in first-line setting in combination with cisplatin and gemcitabine, followed by monotherapy OR Loqtorzi (toripalimab-tpzi) will be used as a single agent for disease progression on or after a platinum-containing regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### LORBRENA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members experience disease progression on Lorbrena (lorlatinib).
Required Medical Information	Non-small cell lung cancer. The member has a diagnosis of metastatic NSCLC with documented anaplastic lymphoma kinase (ALK) positivity AND Lorbrena (lorlatinib) will be given as monotherapy AND one of the following applies in the metastatic setting: as first line therapy AND the member has a medical reason as to why Alecensa (alectinib) or Alunbrig (brigatinib) cannot be initiated or continued as first line therapy OR Subsequent therapy after disease progression on prior ALK inhibitor (e.g., alectinib, brigatinib). Non- small cell lung cancer [ROS-1 rearrangement]: The member has a diagnosis of recurrent, advanced, or metastatic non-small cell lung cancer AND The disease is positive for documented ROS-1 rearrangement and following disease progression on Xalkori (crizotinib), Rozlytrek (entrectinib), or Zykadia (ceritinib) AND Lorbrena (lorlatinib) will be given as a single agent as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

#### LUMAKRAS - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NSLC: Member experienced disease progression on Lumakras. Colorectal Cancer [KRAS G12C-mutated]: Member experienced disease progression on a KRAS G12C inhibitor (e.g., sotorasib, adagrasib).
Required Medical Information	Non-small cell lung cancer (NSCLC): The member has a diagnosis of locally advanced or metastatic NSCLC AND The NSCLC has documented KRAS G12C mutation AND The member has experienced disease progression on one prior therapy AND Lumakras (sotorasib) will be given as monotherapy. Colorectal Cancer [KRAS G12C-mutated]: The member has a diagnosis of metastatic colorectal cancer (mCRC) AND The disease is documented as KRAS G12C-mutated, as determined by an FDA-approved test AND The member has received prior systemic treatment with chemotherapy [fluoropyrimidine-based chemotherapy (e.g., 5-fluorouracil, capecitabine), oxaliplatin, irinotecan] AND Lumakras (sotorasib) will be given in combination with Vectibix (panitumumab).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

# LUNSUMIO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Lunsumio (mosunetuzumab-axgb).
Required Medical Information	Follicular Lymphoma. The member has a diagnosis of follicular lymphoma AND the member has relapsed or refractory disease AND the member has received at least two prior lines of systemic therapy AND the member will be using Lunsumio (mosunetuzumab-axgb) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

## LUPRON DEPOT - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

# LUPRON DEPOT (3 MONTH) - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

# LUPRON DEPOT (4 MONTH) - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

## LUPRON DEPOT (6 MONTH) - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

#### LUPRON DEPOT-PED - KIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

## LUPRON DEPOT-PED (3 MONTH) - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

# LUTRATE DEPOT (3 MONTH) - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents.
Required Medical Information	Prostate Cancer: Diagnosis of advanced prostate cancer or at risk for disease recurrence. Endometriosis: Diagnosis of endometriosis. Fibroids (Uterine leiomyomata). The patient must have a diagnosis of anemia due to uterine leiomymoma. Central Precocious Puberty: Pediatric member with a diagnosis of central precocious puberty (idiopathic or neurogenic). Invasive Breast Cancer: The patient has a diagnosis of hormone responsive (ER and/or PR +) invasive breast cancer AND The patient must be pre or perimenopausal. Recurrent Ovarian Cancer: Patient has recurrent ovarian cancer (epithelial cell cancer, fallopian tube cancer, primary peritoneal cancer or ovarian stromal tumor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration for all except for Endometriosis: 6 months and Uterine Leiomyoma: 3 months
Other Criteria	
Part B Prerequisite	0

### LYBALVI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Use of opioids. Episode of acute opioid withdrawal.
Required Medical Information	Schizophrenia: The member must have a diagnosis of schizophrenia AND The member must have documentation of prior therapy, intolerance, or contraindication to at least one of the following generic atypical antipsychotics: olanzapine, risperidone, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I Disorder (acute manic or mixed, maintenance monotherapy): The member must have a diagnosis of bipolar I disorder (acute manic or mixed, maintenance monotherapy) AND The member must have documentation of prior therapy, intolerance, or contraindication to at least one of the following generic atypical antipsychotics: olanzapine, risperidone, quetiapine, ziprasidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## LYNOZYFIC - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	Pending CMS Review
Exclusion Criteria	Pending CMS Review
Required Medical Information	Pending CMS Review
Age Restriction	Pending CMS Review
Prescriber Restriction	Pending CMS Review
Coverage Duration	Pending CMS Review
Other Criteria	Pending CMS Review
Part B Prerequisite	Pending CMS Review

#### LYNPARZA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following PARP inhibitor therapy [e.g. Rubraca (rucaparib), Lynparza (olaparib), Zejula (niraparib)]. Adjuvant setting for High-Risk Early Breast Cancer: member is taking Lynparza (olaparib) total treatment for more than one year.
Required Medical Information	Breast Cancer (Metastatic): Member has a diagnosis of recurrent or metastatic breast cancer AND Member has deleterious germline or suspected germline BRCA-mutated disease as detected by an FDA- approved test AND Member has HER-2 negative disease, hormone receptor positive or negative, treated with prior chemotherapy and/or endocrine therapy AND Lynparza will be used as subsequent therapy as a single agent. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer First Line Maintenance Therapy: The member has a diagnosis of advanced epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND member's disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation or genomic instability as defined by and FDA approved test. Member is in complete response or partial response to first line treatment with platinum based chemotherapy. Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer Second Line Maintenance Therapy: The member has a diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND The member is in complete or partial response to their last platinum regimen AND The member will utilize Lynparza (olaparib) tablets as monotherapy. *Discontinue Bevacizumab Product before initiating maintenance therapy with Lynparza.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### LYNPARZA - TABLET

#### Other Criteria

Pancreatic Adenocarcinoma - First line maintenance therapy: Member has a diagnosis of metastatic pancreatic adenocarcinoma AND member has deleterious germline or suspected germline BRCA-mutated disease AND member's disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. Metastatic Castration-Resistant Prostate Cancer (mCRPC): Member has a diagnosis metastatic castration-resistant prostate cancer (mCRPC) AND Member will use Lynparza (olaparib) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or concurrent GnRH analog) AND the member has one of the following: Member has documented deleterious or suspected deleterious germline, or somatic homologous recombination repair (HRR) gene-mutated disease AND Member has experienced progressive disease following prior treatment with Xtandi (enzalutamide) or abiraterone OR Member has deleterious germline or suspected germline BRCA-mutated (BRCAm) disease AND Member will use in combination with abiraterone and prednisone or prednisolone. Breast Cancer (Adjuvant): Member has a diagnosis of high-risk early breast cancer AND Member has deleterious germline or suspected germline BRCA-mutated disease as detected by an FDA-approved test AND Member has HER-2 negative disease, hormone receptor positive or negative, treated with prior chemotherapy AND Lynparza will be used as subsequent therapy as a single agent. High Risk early breast cancer defined as patients who: 1. Received prior neoadjuvant chemotherapy: patients with either triple negative breast cancer (TNBC) or hormone receptor positive breast cancer must have had residual invasive cancer in the breast and/or the resected lymph nodes (nonpathologic complete response) at the time of surgery. Additionally, patients with hormone receptor positive breast cancer must have had a score of greater than or equal to 3 based on pretreatment clinical and post-treatment pathologic stage (CPS), estrogen receptor (ER) status, and histologic grade. 2. TNBC with greater than or equal to pT2 or greater than or equal to pN1 prior to adjuvant chemotherapy 3. HR+/HER2-negative with greater than or equal to 4 positive lymph nodes prior to adjuvant chemotherapy. 0 Part B Prerequisite

### LYTGOBI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression on Lytgobi (futibatinib)
Required Medical Information	Cholangiocarcinoma: The member has unresectable locally advanced or metastatic intrahepatic cholangiocarcinoma (iCCA) AND The member has iCCA with documented FGFR2 gene fusions or other rearrangements AND The member has received prior treatment AND Lytgobi (futibatinib) is given as a single agent for subsequent therapy
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

### MARGENZA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Margenza (margetuximab- cmkb).
Required Medical Information	Breast cancer: The member has a diagnosis of metastatic breast cancer AND The disease is documented HER2 neu positive AND The member has received two prior anti-HER2 neu based therapies (including trastuzumab products) where one therapy was given in the metastatic setting AND Margenza (margetuximab-cmkb) is given in combination with chemotherapy (gemcitabine, eribulin, vinorelbine, capecitabine) as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### **MEKINIST - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Melanoma - Unresectable or metastatic: Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Mekinist (trametinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib).] Non- small cell lung cancer, Anaplastic Thyroid Cancer and Metastatic Solid Tumors: Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on prior anti- BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib).] Adjuvant melanoma: member is taking Mekinist (trametinib).] Adjuvant melanoma: member is taking Mekinist (trametinib). I Adjuvant melanoma: member is taking Mekinist (trametinib), or Mektovi (binimetinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib).] Low-grade Glioma: Members that have experienced disease progression while on Mekinist (trametinib). Members that have experienced disease progression while on prior anti- BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib).]

### **MEKINIST - TABLET**

Required Medical Information	Melanoma - Unresectable or Metastatic: The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Mekinist as a single-agent (member has not received prior BRAF- inhibitor therapy) OR in combination with Tafinlar (dabrafenib). Non- small cell lung cancer: The member has a diagnosis of recurrent or metastatic non-small cell lung cancer(NSCLC) AND The member has a documented BRAF V600E mutation AND The member will be using Mekinist (trametinib) in combination with Tafinlar (dabrafenib). Melanoma - Adjuvant. The member has a diagnosis of stage III melanoma AND The member has a diagnosis of stage III melanoma AND The member has a documented BRAF V600 activating mutation AND The member has a documented BRAF V600 activating mutation AND The member has a documented BRAF V600 activating mutation AND The member has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND The member has a documented V600E mutation AND The member has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND The member has a documented V600E mutation AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib). Metastatic Solid Tumors: the member has a diagnosis of unresectable or metastatic solid tumors with documented BRAF V600E mutation AND the member has disease that has progressed on prior therapy and has no satisfactory alternative treatments AND Mekinist is given in combination with Tafinlar. Low-grade Glioma: The member has a diagnosis of low-grade glioma (LGG) AND The member has a documented BRAF V600E mutation AND Mekinist (trametinib) will be used in combination with Tafinlar (dabrafenib).
Age Restriction	Low-grade Glioma only: The member is a pediatric age 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Low-grade Glioma: Plan year duration. All other indications: 6 months duration.
Other Criteria	
Part B Prerequisite	0

### **MEKTOVI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Tafinlar (dabrafenib), or Mekinist (trametinib) OR Members that have experienced disease progression while on prior anti- BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinist (trametinib)].
Required Medical Information	Melanoma - Unresectable or metastatic. The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Braftovi (encorafenib) in combination with Mektovi (binimetinib). Colorectal Cancer - [Braftovi (encorafenib) requests only]: The member has documented BRAFV600E metastatic colorectal cancer and progressive disease on prior therapy AND Braftovi (encorafenib) will be given in combination with Erbitux (cetuximab) OR The member has documented BRAFV600E metastatic colorectal cancer AND Braftovi (encorafenib) will be given in combination with Erbitux (cetuximab) and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin). Metastatic non- small cell lung cancer: The member has documented BRAF V600E metastatic non-small cell lung cancer (NSCLC) AND The member will be using Braftovi (encorafenib) in combination with Mektovi (binimetinib).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month durations
Other Criteria	
Part B Prerequisite	0

### memantine - CAPSULE SPRINKLE, EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Diagnosis of Autism or Atypical Autism (PDD)
Required Medical Information	
Age Restriction	An automatic approval if member is greater than 26 years of age.Prior Auth required for age 26 or younger.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### mifepristone - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hyperglycemia secondary to hypercortisolism. Diagnosis of endogenous Cushing's syndrome. AND Type 2 diabetes mellitus or glucose intolerance. AND Failed surgery or are not candidates for surgery.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### modafinil - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NA
Required Medical Information	Excessive Daytime Sleepiness.For the treatment of excessive daytime sleepiness or hypersomnolence associated with Narcolepsy,obstructive sleep apnea,or due to sleep problems resulting from circadian rhythm disruption (i.e., shift-work sleep disorder). Steinert myotonic dystrophy syndrome.Member must have hypersomnia due to Steinert myotonic dystrophy syndrome.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### molindone - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member must utilize molindone hydrochloride for the management of clinically diagnosed schizophrenia. The member must have documentation of prior therapy, intolerance, or contraindication to two (2) of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### MOUNJARO - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member is using for weight loss.
Required Medical Information	Diabetes Mellitus. The member has a diagnosis of type 2 diabetes mellitus.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### MVASI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Used in lung cancer members that have small cell or squamous cell disease, recent hemoptysis, history of bleeding, continuing anticoagulation, or as a single agent (unless maintenance as described in Coverage Determinations). Should not be initiated in members with recent hemoptysis. Should not be used in members who experience a severe arterial thromboembolic event. Should not be used in members with gastrointestinal perforation. Bevacizumab should not be used in members with fistula formation involving internal organs. Bevacizumab should not be used in members experiencing a hypertensive crisis or hypertensive encephalopathy. Bevacizumab should not be used for at least 28 days following major surgery or until surgical incision is fully healed. Bevacizumab may not be used in conjunction with Vectibix. Bevacizumab may not be used in the adjuvant or neoadjuvant setting (except in epithelial ovarian, fallopian tube, or primary peritoneal cancer adjuvant setting). Bevacizumab should not be continued or restarted after disease progression with the exception of metastatic colorectal cancer.

## MVASI - VIAL (ML)

Required Medical Information	Avastin (bevacizumab), Alymsys (bevacizumab- maly) and Vegzelma (bevacizumab-adcd) oncology requests: must have an intolerance or contraindication with Mvasi or Zirabev. Metastatic colorectal cancer: metastatic colorectal cancer AND 1 of the following apply: using bevacizumab in combo with fluoropyrimidine (e.g., 5- fluorouracil or capecitabine) based chemo for 1st or 2nd-line therapy OR in combo with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin- based chemo for 2nd-line therapy in patients who have progressed on 1st-line bevacizumab-containing regimens. Non-small cell lung cancer (non-squamous cell histology). NSCLC with non-squamous cell histology AND using bevacizumab in combo with cisplatin or carboplatin based regimens for unresectable, locally advanced, recurrent, or metastatic NSCLC AND 1 of the following apply: for 1st line therapy OR as subsequent therapy immediately after 1 of the following situations: EGFR mutation-positive tumors after prior therapy [if cytotoxic therapy not previously given] OR ALK-positive tumors after prior therapy [if cytotoxic therapy not previously given] OR Pembrolizumab (with PD-L1 expression of greater than or equal to 1%) administered as 1st line therapy and EGFR, ALK, BRAF V600E, and ROS1 negative tumors (if cytotoxic therapy not previously given) OR has BRAF V600E positive disease (if cytotoxic therapy not previously given) OR using bevacizumab as single-agent continuation maintenance therapy if bevacizumab was used as 1st line treatment for recurrence or metastasis OR has disease with no EGFR or ALK genomic tumor aberrations AND bevacizumab will be given in combo with carboplatin and paclitaxel and Tecentriq as 1st line therapy followed by maintenance therapy with combo Tecentriq and bevacizumab. Hepatocellular carcinoma: unresectable or metastatic HCC AND used will be used as 1st line therapy in combo with Tecentriq.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### MVASI - VIAL (ML)

#### Other Criteria

Metastatic breast cancer (Effectiveness based on improvement in progression-free survival. No data available demonstrating improvement in disease-related symptoms or survival with bevacizumab). Member has metastatic HER-2 negative breast cancer AND is using bevacizumab in combo with paclitaxel. Recurrent Ovarian Cancer. Bevacizumab is being used to treat recurrent or persistent ovarian cancer for 1 of the following situations: in combo with liposomal doxorubicin or weekly paclitaxel or topotecan for platinum resistant disease or as monotherapy or in combo with carboplatin and gemcitabine for platinum sensitive disease. Stage IV/Metastatic (Unresectable) RCC. Member has RCC and is using bevacizumab to treat stage IV unresectable kidney cancer in combo with interferon alpha OR is using bevacizumab as systemic therapy for nonclear cell histology. Recurrent Primary CNS Tumor (including Glioblastoma multiforme). Diagnosis of progressive or recurrent glioblastoma or anaplastic glioma AND Bevacizumab is being used as a single agent or in combo with irinotecan, carmustine, lomustine or temozolomide. Member does not have a CNS hemorrhage. Soft Tissue Sarcoma. Diagnosis of angiosarcoma and bevacizumab is being used as a single agent OR member has a diagnosis of solitary fibrous tumor and hemangiopericytoma and bevacizumab is being used in combo with temozolomide. Macular Retinal Edema. Avastin is being used to treat central or branch retinal vein occlusion with macular retinal edema. Cervical Cancer: member has recurrent, or metastatic cervical cancer AND Bevacizumab will be used in combo with paclitaxel and cisplatin or carboplatin and paclitaxel or paclitaxel and topotecan as first line therapy. Endometrial Cancer: progressive endometrial cancer AND Bevacizumab will be used as a single-agent. Malignant Pleural Mesothelioma. Diagnosis of unresectable malignant pleural mesothelioma and bevacizumab will be used in combo with cisplatin and pemetrexed followed by bevacizumab monotherapy for maintenance therapy (for responders). Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of epithelial ovarian, fallopian tube or primary peritoneal cancer AND has Stage III or IV disease AND bevacizumab is initially being given in combo with carboplatin and paclitaxel after initial surgical resection followed by bevacizumab monotherapy OR advanced epithelial ovarian, fallopian tube or primary peritoneal cancer AND disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation OR genomic instability as defined by FDA approved test AND Member is in complete response or partial response to 1st line treatment with platinum-based chemo AND Bevacizumab is given in combo with Lynparza. Age Related Macular Degeneration (Avastin requests only). Diabetic Macular Edema (Avastin requests only). 0 Prerequisite

Part B

## MYLOTARG - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression on Mylotarg (gemtuzumab ozogamicin)
Required Medical Information	Acute Myelogenous Leukemia: The member has a diagnosis of acute myeloid leukemia (AML) AND the member has documented CD33- positive disease AND One of the following applies: the member has newly-diagnosed disease and is an adult or pediatric patient one month or older OR the member has relapsed/refractory disease and is an adult or pediatric patient 2 years and older.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Newly dx AML:6 months(max 1 cycle induction-8 cycles consolidation) Rel/Ref AML:3months(max 1 cycle)
Other Criteria	NA
Part B Prerequisite	0

#### NERLYNX - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has disease progression on Nerlynx (neratinib). Member is taking Nerlynx (neratinib) total treatment for more than one year [applicable only to early stage breast cancer].
Required Medical Information	Early stage Breast Cancer: Initial Therapy. The member has early stage (i.e. Stage I, II, III) documented HER2 + positive disease AND The member has completed adjuvant therapy with a trastuzumab containing treatment AND Nerlynx (neratinib) is being used for the treatment in extended adjuvant setting. Continuation of therapy. The member is not experiencing any of the following situations: Grade 4 any adverse event [e.g., diarrhea, ALT (greater than 20 times ULN), bilirubin (greater than 10 times ULN)], Greater than or equal to grade 2 diarrhea with Nerlynx (neratinib) dosing of 120mg per day AND If any of the above severe adverse reactions have been experienced, then provider has given a rationale for benefit of continued use that outweighs risk. Metastatic Breast Cancer. The member has metastatic or advanced breast cancer and all of the following apply: The member has documented HER2 positive disease and The member has received two or more prior anti- HER2 based regimens in the metastatic setting and Nerlynx (neratinib) is given in combination with capecitabine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Early stage: Initial - 3 months, Continuation therapy- 9 months. Metastatic or advanced: 6 months
Other Criteria	
Part B Prerequisite	0

### nilotinib hcl - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Tasigna (nilotinib). For ALL and CML: The member has one of the following mutations: T315I, Y253H, E255K/V, or F359V/C/I.
Required Medical Information	Chronic Myelogenous Leukemia (CML). The member has a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (CML) AND One of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated, and one of the following applies: Intermediate- or high-risk score for disease progression OR Low-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib OR The members has a diagnosis of chronic phase CML that has received previous treatment. Advanced Gastrointestinal Stromal Tumor (GIST). Diagnosis of advanced unresectable GIST.The member has progressive disease or is intolerant to prior therapy with Gleevec (imatinib), Sutent (sunitinib), or Stivarga. Acute Lymphoblastic Leukemia (ALL). The member has diagnosis of Philadelphia positive acute lymphoblastic leukemia. Pediatric CML: Diagnosis of chronic phase Ph+ chronic myeloid leukemia (CML) OR Diagnosis of accelerated phase Ph+ chronic myeloid leukemia (CML) AND resistance, intolerance, or contraindication to prior TKI therapy.
Age Restriction	Pediatric CML- member is greater than or equal to 1 year of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### nilotinib tartrate - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on any nilotinib (e.g. Tasigna, Danziten).
Required Medical Information	Chronic Myeloid Leukemia: The member has a diagnosis of Philadelphia Chromosome positive (Ph+) chronic myeloid leukemia (CML) AND One of the following: CML is in chronic phase OR CML is accelerated phase and if accelerated phase member is resistant to or intolerant to prior therapy that included imatinib.
Age Restriction	The member is 18 years or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **NINLARO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with disease progression on Ninlaro (ixazomib).
Required Medical Information	Multiple Myeloma: second line. The member has a diagnosis of relapsed or refractory multiple myeloma AND Ninlaro (ixazomib) will be used after disease progression on at least one prior therapy AND Ninlaro (ixazomib) will be used in combination with either dexamethasone OR lenalidomide and dexamethasone or cyclophosphamide and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication). Multiple Myeloma: third line or subsequent. The member has a diagnosis of relapsed or refractory multiple myeloma AND Ninlaro (ixazomib) will be used after disease progression on at least two prior therapies AND Ninlaro (ixazomib) will be used in combination with pomalidomide and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The members has demonstrated disease progression on or within 60 days of completion of the last therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

### NIVESTYM - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim product or pegfilgrastim product (e.g., filgrastim, filgrastim-sndz, filgrastim-aafi, pegfilgrastim-jmbd, pegfilgrastim-cbqv) within seven days of pegfilgrastim dose.
Required Medical Information	Neutropenia in Myelodysplastic Syndromes. The member must have a diagnosis of neutropenia associated with myelodysplastic syndrome. Treatment of Febrile Neutropenia: The member must have a diagnosis of febrile neutropenia AND filgrastim product must be used in adjunct with appropriate antibiotics in high risk members. Febrile Neutropenia Prophylaxis: The member must have a diagnosis of non-myeloid malignancy (e.g., solid tumors) AND The member has received or will receive filgrastim product 24-72 hours after the administration of myelosuppressive chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and at least ONE of the following risk factors apply OR A risk of febrile neutropenia of less than 10% based on chemotherapy regimen, and at least TWO of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration

### NIVESTYM - VIAL (ML)

Other Criteria	Febrile Neutropenia Prophylaxis, in members with acute myeloid leukemia receiving chemotherapy: The member must have a diagnosis Acute Myeloid Leukemia (AML). The member must be receiving either induction chemotherapy QR consolidation Chemotherapy AND The member is not administering filgrastim product earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy. Febrile Neutropenia Prophylaxis, In non-myeloid malignancies following Hematopoietic Stem Cell Transplant (HCST): The member must have had a Hematopoietic Stem Cell Transplant (HCST) (e.g. bone marrow transplant, peripheral-blood progenitor cell (PBPC) transplant) for a non- myeloid malignancy AND The member is not administering filgrastim product earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy Harvesting of peripheral blood stem cells.The member must be scheduled for autologous peripheral-blood stem cell (PBSC) transplant, or donating stem cells for a possible future autologous transplant, or donating stem cells for an allogeneic or syngeneic PBSC transplant. Neutropenic disorder, chronic (Severe), Symptomatic: The member must have a diagnosis of congenital, cyclic, or idiopathic neutropenia. Neutropenia in AIDS patients. The member must have a diagnosis of AIDS with neutropenia. Treatment of Aplastic Anemia. The member must have a diagnosis of Aplastic Anemia. Treatment of Agranulocytosis.The member must have a diagnosis of congenital or drug induced agranulocytosis. Hematopoietic Syndrome of Acute radiation syndrome. The member has been acutely exposed to myelosuppressive doses of radiation.
Part B Prerequisite	0

#### NUBEQA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Nubeqa (darolutamide).
Required Medical Information	Prostate Cancer (non-metastatic castration-resistant): The member has a diagnosis of non-metastatic castration-resistant prostate cancer AND the member will use Nubeqa (darolutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog). Prostate Cancer (metastatic hormone-sensitive prostate cancer): The member has a diagnosis of metastatic hormone-sensitive prostate cancer AND the member will use Nubeqa (darolutamide) in combination with docetaxel AND the member will use Nubeqa (darolutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## NUCALA - AUTO-INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Severe Asthma with an Eosinophilic Phenotype: The member has a diagnosis of severe asthma AND the member has an eosinophilic phenotype, defined by an elevated peripheral blood eosinophil level of greater than or equal to 150 cells/microliter at therapy initiation OR greater than or equal to 300 cells/microliter in the previous 12 months. The member has been unable to achieve adequate control of asthma while on maximum tolerated inhaled corticosteroid therapy (e.g. mometasone greater than 400mcg daily, fluticasone greater than 440 mcg daily) in combination with a long acting beta agonist (e.g. formoterol). Eosinophilic Granulomatosis with Polyangiitis (EGPA) - Nucala and Fasenra only: The member has a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA) AND the member has a baseline elevated peripheral blood eosinophil level of greater than 10% of total leukocyte count AND The member has been unable to achieve adequate control of EGPA while on oral corticosteroid therapy (e.g. prednisone, methylprednisolone). Hypereosinophilic Syndrome (HES) - Nucala only: The member has a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophil level of greater than a baseline blood eosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophil level of greater than a baseline blood eosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than a baseline blood eosinophil level of greater than a diagnosis of hypereosinophilic syndrome (HES) for at least 6 months AND The member has a baseline blood eosinophil level of greater than or equal to 1000 cells/microliter.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Chronic Rhinosinusitis with Nasal Polyposis - Nucala Only: The member must meet ALL of the following criteria: Diagnosis of Chronic Rhinosinusitis with Nasal Polyposis AND Nucala (mepolizumab) will be used in conjunction with a daily intranasal corticosteroid spray AND member is unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy.
Part B Prerequisite	0

#### **NUEDEXTA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pseudobulbar Affect: The member has a diagnosis of Pseudobulbar Affect (PBA) due to brain injury or underlying neurologic disease (e.g., stroke, multiple sclerosis, ALS, Parkinson's disease, traumatic brain injury) AND The member is experiencing characteristic behavior episodes (e.g inappropriate laughing or crying) consistent with PBA at baseline AND the provider attests that the risk of QT prolongation with Nuedexta has been considered, and benefits of treatment outweigh risks.
Age Restriction	Member must be 18 years of age or older
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### NUPLAZID - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Parkinson's Disease Psychosis: The member is using Nuplazid for the treatment of hallucinations and delusions associated with Parkinson's disease (PD) psychosis AND the symptoms of psychosis have appeared after the diagnosis of PD AND psychosis is not related to other causes other than PD.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### nyamyc - POWDER (GRAM)

	Critoria Dataila
PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### nystatin - POWDER (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# nystop - POWDER (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Member must be using topically for the treatment active cutaneous or mucocutaneous candidiasis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# octreotide acetate - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Acromegaly: The member must have a diagnosis of Acromegaly. Must have had an inadequate response to surgery/radiation or for whom surgical resection/radiation is not an option. Treatment of metastatic carcinoid tumors. Must have a diagnosis of a carcinoid tumor. Patient must have severe diarrhea and flushing resulting from carcinoid tumor. Treatment of vasoactive intestinal peptide tumors (VIPomas). Patient must be diagnosed with a vasoactive intestinal peptide tumor. Patient must have diagnosis of profuse watery diarrhea associated with VIP- secreting tumor. Treatment of chemotherapy or radiation induced diarrhea. Patient must have grade 3 or above diarrhea according to NCI common toxicity. Patient must have NCI grade 1 or 2 diarrhea and have failed treatment with loperamide or diphenoxylate and atropine. Treatment of severe secretory diarrhea in acquired immune deficiency syndrome (AIDS) patients. Patient must have diagnosis of severe diarrhea resulting from acquired immune deficiency syndrome (AIDS). Patient must have tried and failed antimicrobial agents (eg. ciprofloxacin or metronidazole) and/or anti-motility agents (eg. loperamide or diphenoxylate and atropine). Reversal of life-threatening hypotension due to carcinoid crisis during induction of anesthesia. Patient must have life-threatening hypotension due to carcinoid crisis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# octreotide, microspheres - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Acromegaly: The member must have a diagnosis of Acromegaly. Must have had an inadequate response to surgery/radiation or for whom surgical resection/radiation is not an option. Treatment of metastatic carcinoid tumors. Must have a diagnosis of a carcinoid tumor. Patient must have severe diarrhea and flushing resulting from carcinoid tumor. Treatment of vasoactive intestinal peptide tumors (VIPomas). Patient must be diagnosed with a vasoactive intestinal peptide tumor. Patient must have diagnosis of profuse watery diarrhea associated with VIP- secreting tumor. Treatment of chemotherapy or radiation induced diarrhea. Patient must have grade 3 or above diarrhea according to NCI common toxicity. Patient must have NCI grade 1 or 2 diarrhea and have failed treatment with loperamide or diphenoxylate and atropine. Treatment of severe secretory diarrhea in acquired immune deficiency syndrome (AIDS) patients. Patient must have diagnosis of severe diarrhea resulting from acquired immune deficiency syndrome (AIDS). Patient must have tried and failed antimicrobial agents (eg. ciprofloxacin or metronidazole) and/or anti-motility agents (eg. loperamide or diphenoxylate and atropine). Reversal of life-threatening hypotension due to carcinoid crisis during induction of anesthesia. Patient must have life-threatening hypotension due to carcinoid crisis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### **ODOMZO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Odomzo.
Required Medical Information	Basal Cell Carcinoma: The member has a diagnosis of locally advanced or metastatic basal cell carcinoma AND The member has experienced recurrence or disease progression following surgery or radiation OR has a contraindication to surgery or radiation.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	NA
Part B Prerequisite	0

#### **OFEV - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype: The member has a diagnosis of a Chronic Fibrosing Interstitial Lung Disease [ILD] (e.g., Idiopathic Pulmonary Fibrosis [IPF], Hypersensitivity pneumonitis, Autoimmune ILD, Rheumatoid arthritis- associated ILD [RA-ILD], Systemic Sclerosis-associated ILD [SSc-ILD], Mixed Connective Tissue Disease-associated ILD, Idiopathic non- specific interstitial pneumonia, Unclassifiable Idiopathic Interstitial Pneumonia, Exposure-related ILDs, Sarcoidosis with Fibrosing ILD, in addition to other chronic fibrosing ILDs) confirmed by one of the following: Computer Tomography (CT) with evidence of fibrosis OR Lung Biopsy. Member has a progressive phenotype confirmed by one of the following: Diagnosis is for Idiopathic Pulmonary Fibrosis OR Has had a relative decline in FVC of at least 10% OR worsening respiratory symptoms OR increased extent of fibrotic change on CT scan.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **OGSIVEO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has had disease progression on Ogsiveo (nirogacestat).
Required Medical Information	Desmoid tumors: Member has been diagnosed with progressing desmoid tumor (progressing desmoid tumors are defined as greater than or equal to 20% progression based on Response Evaluation Criteria in Solid Tumors [RECIST] within 12 months) AND Member will be using Ogsiveo (nirogacestat) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### OJEMDA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on Ojemda (tovorafenib).
Required Medical Information	Pediatric Low-Grade Glioma (pLGG): The member has a diagnosis of relapsed or refractory pediatric low-grade glioma (LGG) AND The member has a documented BRAF fusion or rearrangement, or documented BRAF V600E mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### OJJAARA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Ojjaara (momelotinib).
Required Medical Information	Myelofibrosis - Initial: The member has a diagnosis of primary myelofibrosis or secondary myelofibrosis (i.e. post-polycythemia vera or post-essential thrombocythemia) AND The member has one of the following risk categories, as defined by accepted risk stratification tools for myelofibrosis (e.g. International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or DIPSS- PLUS): Intermediate-risk disease OR High-risk disease AND The member has anemia* AND The member will be using Ojjaara (momelotinib) as monotherapy AND The member has tried, intolerant to, or has a contraindication to Jakafi (Ruxolitinib) or has hemoglobin less than 8 g/dL. *Anemia is defined as hemoglobin less than 10 g/dL or having transfusion-dependent anemia. Myelofibrosis - Reauthorization: Physician attestation that the member has continued to receive a clinical benefit (e.g. spleen volume reduction from baseline, symptom improvement) AND Physician attestation that the member has not experienced unacceptable toxicities.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial auth and Reauthorization: 6 months duration
Other Criteria	
Part B Prerequisite	0

# OMNITROPE - CARTRIDGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	GH Therapy in Adults (18 or older). Must have previous tx with Omnitrope. Adult-onset GHD either alone or with multiple hormone deficiencies (hypopituitarism) as a result of pituitary, hypothalamic disease, surgery, radiation, or trauma OR has a diagnosis of childhood- onset GHD. A subnormal response to two standard GH stimulation tests (1 must be insulin tolerance test [ITT]). If contraindication to ITT, a subnormal response to a standardized stimulation tests must be provided along with Insulin like growth factor. Acceptable tests are ITT,glucagon, and macimorelin test. Assay type must be documented. Subnormal response to ITT is defined as peak serum GH level less than or equal to 5 ng/ml. Subnormal response to glucagon stimulation test is: Less than or equal to 3 mcg/L in patients with a BMI of less than 25 kg/m2 OR Less than or equal to 3 mcg/L in patients with a BMI of 25 - 30 kg/m2 and high pre-test probability, Less than or equal to 1 mcg/L in patients with a BMI of 25 - 30 kg/m2 and a low pre-test probability OR Less than or equal to 1 mcg/L in patients with a BMI of greater than 30 kg/m2. Subnormal response to the macimorelin test is defined as peak serum GH level less than or equal to 2.8 mcg/L. For ITT, blood glucose nadir of less than 40mg/dL must be documented. Certain patient subtypes (e.g. those with organic hypothalamic-pituitary disease and biochemical evidence of multiple pituitary hormone deficiencies (MPHD)) together with low-serum IGF-1 levels (less than -2.0 standard deviation score [SDS]) with genetic defects affecting the hypothalamic-pituitary axes, and hypothalamic- pituitary structural brain defects, can be diagnosed with adult GHD without performing GH-stimulation test. In patients with less than or equal to 2 pituitary hormone deficiencies, low-serum IGF-1 levels (less than -2.0 SDS) alone are not enough for a diagnosis of adult GHD, one GH-stimulation test is required to confirm the diagnosis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### **OMNITROPE - CARTRIDGE (ML)**

**Other Criteria** GHT in Children (less than 18). GH failure associated with GH deficiency. Bone age is at least 1 year or 2 SDs delayed compared to chronological age AND epiphyses not closed. Growth rate is less than: 4.5 cm/yr for age over 4, 7cm/yr for ages 2-4, 9 cm/yr for ages 1-2. Two GH stimulation test results with GH secretion less than 10 ng/ml. Acceptable tests include L-dopa, arginine, clonidine, glucagon, exercise, insulin-induced hypoglycemia. Small for gestational age. Born small for gestational age, defined as birth weight or length 2 or more SDs below the mean for gestational age: and fails to catch up growth by age 2 years, defined as height 2 or more SDs below the mean for age and sex.Short Stature Homeobox-Containing Gene (SHOX) Deficiency. Children with SHOX deficiency whose epiphyses are not closed. Chronic Renal insufficiency. Children with CRI and growth retardation who meet both: metabolic abnormalities have been corrected, and steroid usage has been reduced to a minimum AND At least 1 of the following criteria is met: has severe growth retardation with height SDS more than 3 SDS below the mean for chronological age and sex: OR has moderate growth retardation with height SDS between -2 and -3 SDS below the mean for chronological age and sex and decreased growth rate (GV measured over 1 year below 25th percentile for age and sex): OR Child exhibits severe deceleration in growth rate (GV measured over 1 year -2 SDS below the mean for age, sex). Prader-Willi Syndrome or Turner's Syndrome. Diagnosis of growth failure due to Prader-Willi syndrome OR Diagnosis of short stature associated with Turner's syndrome AND At least 1 of the following: severe growth retardation with height SDS more than 3 SDS below the mean for chronological age and sex: OR Child has moderate growth retardation with height SDS between -2 and -3 SDS below the mean for chronological age and sex and decreased growth rate (GV measured over 1 year below 25th percentile for age and sex): OR Child exhibits severe deceleration in growth rate (GV measured over 1 year -2 SDS below the mean for age and sex). For Prader Willi Syndrome only: Is not severely obese or has a severe respiratory impairment . Noonan Syndrome. Height 2 SDS or more below the mean for chronological age and sex: AND GV measured over 1 year prior to initiation of therapy of 1 or more SDS below the mean for age and sex. 0 Part B Prerequisite

# ONCASPAR - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following Oncaspar. Members with a history of serious thrombosis with prior asparaginase therapy. Members with a history of pancreatitis with prior asparaginase therapy. Members with a history of serious hemorrhagic events with prior asparaginase therapy. Members with total bilirubin more than 10 times the upper limit of normal.
Required Medical Information	Acute Lymphoblastic Leukemia: The member has a diagnosis of acute lymphoblastic leukemia (ALL) AND the member will be using Oncaspar (pegaspargase) as a component of a multi-agent chemotherapy regimen.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA
Part B Prerequisite	0

# ONIVYDE - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Monotherapy with Onivyde (liposomal irinotecan). Members that have experienced disease progression while on Onivyde (liposomal irinotecan).
Required Medical Information	Pancreatic Cancer (First-line Therapy): The member has a diagnosis of metastatic adenocarcinoma of the pancreas AND Onivyde (liposomal irinotecan) will be used as first-line therapy AND The member will be using Onivyde (liposomal irinotecan) in combination with oxaliplatin, fluorouracil and leucovorin. Pancreatic Cancer (Subsequent Therapy): The member has a diagnosis of metastatic adenocarcinoma of the pancreas AND The member has previously received gemcitabine based therapy or fluoropyrimidine based therapy (not including irinotecan) and experienced disease progression AND The member will be using Onivyde (liposomal irinotecan) in combination with fluorouracil and leucovorin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **ONUREG - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	The member has experienced disease progression on hypomethylators (e.g. azacitidine, decitabine).
Required Medical Information	Acute Myeloid Leukemia: The member has a diagnosis of acute myeloid leukemia AND The member is using Onureg (azacitidine) for post- remission therapy AND The member has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy AND The member is not able to complete or declines intensive curative therapy (e.g. allogeneic hematopoietic stem cell transplant) AND The member will use Onureg (azacitidine) as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA
Part B Prerequisite	0

# OPDIVO - VIAL (ML)

Off-Label Uses           Exclusion Criteria         All indications except Hepatocellular carcinoma, MSI-H or dMMR: Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Bavencio [avelumab]). Adjuvant melanoma only: member is taking Opdivo (nivolumab) total treatment for more than one year. Neoadjuvant NSCLC only: member is taking Opdivo (nivolumab) total treatment in combination with platinum-doublet chemotherapy for more than 3 cycles. Hepatocellular carcinoma: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Imjudo [tremelimumab-act]] with Imfinzi [durvalumab]). MSI-H or dMMR: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Opdivo [nivolumab] with Yervoy [ipilimumab].           Required Medical Information         Melanoma: diagnosis of unresectable or metastatic melanoma AND using as monotherapy OR in combo with Yervoy (ipilimumab) followed by Opdivo (nivolumab) or Opdivo Qvantig (nivolumab and hyaluronidase- nvhy) monotherapy. Melanoma-Adjuvant: diagnosis of stage IIB, IIC, III or stage IV melanoma AND undergone complete resection of disease AND using as adjuvant treatment AND using as monotherapy. Non- Small Cell Lung Cancer-subsequent therapy: diagnosis of metastatic squamous or non-squamous NSCLC AND experienced disease progression on or after chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND using as monotherapy. Renal Cell Carcinoma at RCC): diagnosis of advanced RCC AND one of the following applies: will be using in combo with 2 aboveqy as first line therapy OR Will be using as subsequent therapy as first line therapy OR Will be using as monotherapy as first line therapy OR Will be using as monotherapy as first line therapy OR Will be using as monotherapy as first line therapy OR Will be using as monotherapy or orobit with a supported combo therapy OR has newhy d	PA Criteria	Criteria Details
Criteria         Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant melanoma only: member is taking Opdivo (nivolumab) total treatment for more than one year. Neoadjuvant NSCLC only: member is taking Opdivo (nivolumab) total treatment in combination with platinum-doublet chemotherapy for more than 3 cycles. Hepatocellular carcinoma: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Imjudo [tremelimumab-actl] with Imfinzi [durvalumab]). MSI-H or dMMR: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Opdivo [nivolumab] with Yervoy [ipilimumab].           Required Medical Information         Melanoma: diagnosis of unresectable or metastatic melanoma AND using as monotherapy OR in combo with Yervoy (ipilimumab) followed by Opdivo (nivolumab) or Opdivo Qvantig (nivolumab and hyaluronidase- nvhy) monotherapy. Melanoma-Adjuvant: diagnosis of stage IIB, IIC, III or stage IV melanoma AND undergone complete resection of disease AND using as adjuvant treatment AND using as monotherapy. Non- Small Cell Lung Cancer-subsequent therapy: diagnosis of metastatic squamous or non-squamous NSCLC AND experienced disease progression on or after chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND using as monotherapy. Renal Cell Carcinoma (RCC): diagnosis of advanced RCC AND one of the following applies: will be using as subsequent therapy as first line therapy OR Will be using in combo with Cabometyx (cabozantinib) as first line therapy. Classical Hodgkin Lymphoma: diagnosis of classical Hodgkin Lymphoma AND one of the following applies: has relapsed or refractory disease AND using as monotherapy or in combo with a supported combo therapy OR has newly diagnosed disease AND using in combo with doxorubicin, vinblastine and dacarbazine. Non-Sm	Off-Label Uses	
Medical Information using as monotherapy OR in combo with Yervoy (ipilimumab) followed by Opdivo (nivolumab) or Opdivo Qvantig (nivolumab and hyaluronidase- nvhy) monotherapy. Melanoma-Adjuvant: diagnosis of stage IIB, IIC, III or stage IV melanoma AND undergone complete resection of disease AND using as adjuvant treatment AND using as monotherapy. Non- Small Cell Lung Cancer-subsequent therapy: diagnosis of metastatic squamous or non-squamous NSCLC AND experienced disease progression on or after chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND using as monotherapy. Renal Cell Carcinoma (RCC): diagnosis of advanced RCC AND one of the following applies: will be using as subsequent therapy AND has received prior anti-angiogenic therapy OR Will be using in combo with Yervoy followed by Opdivo or Opdivo Qvantig monotherapy as first line therapy OR Will be using as monotherapy as first line therapy OR Will be using as monotherapy or in combo with Yervoy followed by Opdivo or Opdivo Qvantig applies: has relapsed or refractory disease AND using as monotherapy or in combo with a supported combo therapy OR has newly diagnosed disease AND using in combo with doxorubicin, vinblastine and dacarbazine. Non-Small Cell Lung Cancer (NSCLC)-Perioperative: diagnosis of NSCLC AND must not have any known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements AND must have resectable disease (tumors greater than or equal to 4 cm or node positive) AND using in the neoadjuvant setting, in combo with plainum- doublet chemo followed by Opdivo or Opdivo Qvantig as monotherapy. Hepatocellular Carcinoma: The member has a diagnosis of hepatcellular carcinoma AND using in combo with Yervoy followed by Opdivo or Opdivo Qvantig monotherapy.		Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant melanoma only: member is taking Opdivo (nivolumab) total treatment for more than one year. Neoadjuvant NSCLC only: member is taking Opdivo (nivolumab) total treatment in combination with platinum-doublet chemotherapy for more than 3 cycles. Hepatocellular carcinoma: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Imjudo [tremelimumab-actl] with Imfinzi [durvalumab]). MSI-H or dMMR: Disease progression while on or following anti-PD-1/PD-L1 combination
Age Restriction	Medical	Melanoma: diagnosis of unresectable or metastatic melanoma AND using as monotherapy OR in combo with Yervoy (ipilimumab) followed by Opdivo (nivolumab) or Opdivo Qvantig (nivolumab and hyaluronidase- nvhy) monotherapy. Melanoma-Adjuvant: diagnosis of stage IIB, IIC, III or stage IV melanoma AND undergone complete resection of disease AND using as adjuvant treatment AND using as monotherapy. Non- Small Cell Lung Cancer-subsequent therapy: diagnosis of metastatic squamous or non-squamous NSCLC AND experienced disease progression on or after chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND using as monotherapy. Renal Cell Carcinoma (RCC): diagnosis of advanced RCC AND one of the following applies: will be using as subsequent therapy and has received prior anti-angiogenic therapy OR Will be using in combo with Yervoy followed by Opdivo or Opdivo Qvantig monotherapy as first line therapy OR Will be using in combo with Cabometyx (cabozantinib) as first line therapy. Classical Hodgkin Lymphoma: diagnosis of classical Hodgkin Lymphoma AND one of the following applies: has relapsed or refractory disease AND using as monotherapy or in combo with a supported combo therapy OR has newly diagnosed disease AND using in combo with doxorubicin, vinblastine and dacarbazine. Non-Small Cell Lung Cancer (NSCLC)-Perioperative: diagnosis of NSCLC AND must not have any known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements AND must have resectable disease (tumors greater than or equal to 4 cm or node positive) AND using in the neoadjuvant setting, in combo with platinum- doublet chemo followed by Opdivo or Opdivo Qvantig as monotherapy. Hepatocellular Carcinoma: The member has a diagnosis of hepatcellular carcinoma AND using in combo with Yervoy followed by Opdivo or
	Age Restriction	

# OPDIVO - VIAL (ML)

Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

#### **OPDIVO - VIAL (ML)**

#### Other Criteria

Non-nasopharyngeal recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) AND using as monotherapy AND disease progression on or after platinum based therapy. Locally advanced or metastatic urothelial cancer AND using as monotherapy AND 1 of the following apply: used as 2nd or subsequent line-therapy OR Disease progression within 12 months of neoadjuvant or adjuvant chemo OR high risk of recurrence after radical surgical resection of disease. Unresectable or metastatic colorectal cancer with documented Microsatellite Instability-High (MSI-H) or Mistmatch Repair Deficient (dMMR) AND 1 of the following applies: disease progressed following treatment with oxaliplatin-, irinotecan-, or fluoropyrimidine-based therapy and will be using Opdivo or Opdivo Qvantig as monotherapy OR using in combo with Yervoy, followed by Opdivo or Opdivo Qvantig as monotherapy. Non-small cell lung cancer (NSCLC) 1st Line Therapy: metastatic NSCLC AND 1 of the following applies: Disease with PD-L1 expression greater than or equal to 1% with no EGFR or ALK genomic tumor aberrations and given as 1st line therapy AND Tumor expresses PD-L1 as determined by FDA-approved test AND in combo with Yervoy OR Disease with no EGFR or ALK genomic tumor aberrations and given as 1st line therapy AND in combo with Yervoy AND used in combo with 2 cycles of platinum doublet chemo. Esophageal cancer: unresectable advanced, recurrent, or metastatic squamous cell carcinoma of the esophagus and 1 of the following apply: disease progressed after prior fluoropyrimidine- and platinum-based chemo AND will be given as subsequent monotherapy OR in combo with fluoropyrimidine- and platinum containing chemo for 1st line treatment AND the tumor expressed PD-L1 great than or equal to 1 OR as 1st line treatment Opdivo in combo with Yervoy AND the tumor expressed PD-L1 great than or equal. Unresectable malignant pleural mesothelioma AND 1 of the following scenarios applies: 1st-line treatment AND in combo with Yervoy OR as subsequent treatment, if not administered 1st-line AND as single agent OR in combo with Yervoy. Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal Adenocarcinoma (advanced or metastatic): given with a regimen containing fluoropyrimidine- and platinum-based chemo AND the tumor expressed PD-L1 great than or equal. Esophageal or Gastroesophageal Junction cancer (residual disease post-surgery and preoperative chemoradiation): received neoadjuvant chemoradiation AND complete surgical resection of esophageal or gastroesophageal junction AND has residual pathologic disease AND given as subsequent monotherapy. NSCLC- Neoadjuvant Therapy: early stage NSCLC AND has resectable disease (tumors greater than 4 cm or node positive) AND using in neoadjuvant setting, in combo with platinum-doublet chemo. Hepatocellular carcinoma AND in combo with Yervov followed by Opdivo or Opdivo Qvantig monotherapy. 0 Prerequisite

Part B

# OPDIVO QVANTIG - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	All indications except Hepatocellular carcinoma, MSI-H or dMMR: Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant melanoma only: member is taking Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) total treatment for more than one year. Neoadjuvant NSCLC only: member is taking Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) total treatment in combination with platinum-doublet chemotherapy for more than 3 cycles. Hepatocellular carcinoma: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Imjudo [tremelimumab-actl] with Imfinzi [durvalumab]). MSI-H or dMMR: Disease progression while on or following anti-PD-1/PD-L1 combination therapy (e.g. Opdivo [nivolumab] with Yervoy [ipilimumab].
Required Medical Information	Melanoma: diagnosis of unresectable or metastatic melanoma AND using as monotherapy OR Opdivo (nivolumab) in combo with Yervoy (ipilimumab) followed by Opdivo Qvantig (nivolumab and hyaluronidase- nvhy) monotherapy. Melanoma-Adjuvant: diagnosis of stage IIB, IIC, III or stage IV melanoma AND undergone complete resection of disease AND using as adjuvant treatment AND using as monotherapy. Non- Small Cell Lung Cancer-subsequent therapy: diagnosis of metastatic squamous or non-squamous NSCLC AND experienced disease progression on or after chemo and EGFR inhibitor, if EGFR mutation positive or ALK inhibitor, if ALK positive AND using as monotherapy. Renal Cell Carcinoma (RCC): diagnosis of advanced RCC AND one of the following applies: will be using as subsequent therapy AND has received prior anti-angiogenic therapy OR Opdivo (nivolumab)using in combo with Yervoy followed by Opdivo Qvantig monotherapy as first line therapy OR Will be using in combo with Cabometyx (cabozantinib) as first line therapy. Non-Small Cell Lung Cancer (NSCLC)-Perioperative: diagnosis of NSCLC AND must not have any known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements AND must have resectable disease (tumors greater than or equal to 4 cm or node positive) AND using in the neoadjuvant setting, in combo with platinum-doublet chemo followed by Opdivo or Opdivo Qvantig as monotherapy. Hepatocellular Carcinoma: The member has a diagnosis of hepatcellular carcinoma AND Opdivo (nivolumab) using in combo with Yervoy, followed by Opdivo Qvantig monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner

# OPDIVO QVANTIG - VIAL (ML)

Coverage Duration	6 months duration
Other Criteria	Non-nasopharyngeal recurrent or metastatic Squamous Cell Carcinoma of the Head and Neck (SCCHN) AND using as monotherapy AND disease progression on or after platinum based therapy. Locally advanced or metastatic urothelial cancer AND using as monotherapy AND 1 of the following apply: used as 2nd or subsequent line-therapy OR Disease progression within 12 months of neoadjuvant or adjuvant chemo OR high risk of recurrence after radical surgical resection of disease. Unresectable or metastatic urothelial cancernom AND in combo with cisplatin and gemcitabine, followed by monotherapy maintenance. Unresectable or metastatic colorectal cancer with documented Microsatellite Instability-High (MSI-H) or Mistmatch Repair Deficient (dMMR) AND 1 of the following applies: disease progressed following treatment with oxaliplatin-, irinotecan-, or fluoropyrimidine-based therapy and will be as monotherapy OR Opdivo (nivolumab) using in combo with Yervoy, followed by Opdivo Qvantig as monotherapy. Non-small cell lung cancer (NSCLC) 1st Line Therapy: metastatic NSCLC AND 1 of the following applies: Disease with PD-L1 expression greater than or equal to 1% with no EGFR or ALK genomic tumor aberrations and given as 1st line therapy AND Tumor expresses PD-L1 as determined by FDA-approved test OR Disease with no EGFR or ALK genomic tumor aberrations and given as 1st line therapy AND used in combo with 2 cycles of platinum doublet chemo. Esophageal cancer: unresectable advanced, recurrent, or metastatic squamous cell carcinoma of the esophagus and 1 of the following apply: disease progressed After prior fluoropyrimidine- and platinum-based chemo AND with fluoropyrimidine- and platinum-based chemo AND the tumor expressed PD-L1 great than or equal to 1. Gastric Cancer, Gastroesophageal Junction Cancer, and Esophageal or Gastroesophageal Junction cancer (residual disease post-surgery and preoperative chemoradiation): received neoadjuvant chemo abused therapy. NSCLC - Neoadjuvant thar or equal. Esophageal junction AND has residual patholog
Prerequisite	

# OPDUALAG - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following prior anti-PD-1/PD-L1 combination therapy (e.g., nivolumab with ipilimumab). Members on concomitant Zelboraf (vemurafenib), Tafinlar (dabrafenib), Mekinist (trametinib) or Cotellic (cobimetinib) therapy. Safety and efficacy have not been established.
Required Medical Information	Melanoma: Unresectable or metastatic melanoma: The member must have a diagnosis of unresectable or metastatic melanoma AND Opdualag is administered as monotherapy.
Age Restriction	The member must be 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### OPIPZA - FILM, MEDICATED (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member has clinically diagnosed schizophrenia AND The member has tried or cannot use generic aripiprazole AND The member has tried or cannot use at least one of the following generic atypical antipsychotics: risperidone, olanzapine, quetiapine, ziprasidone, or lurasidone. Major Depressive Disorder (MDD): The member has clinically diagnosed major depressive disorder (MDD) AND The member has tried or cannot use generic aripiprazole in combination with at least one product considered antidepressant therapy (ADT) AND Opipza will be used as adjunctive or add-on treatment to ADT and not as monotherapy. Irritability associated with Autistic Disorder or Tourette's Disorder: The member has one of the following clinically diagnosed conditions: Irritability associated with autistic disorder OR Tourette's disorder AND The member has tried or cannot use generic aripiprazole.
Age Restriction	Schizophrenia: The member is 13 years of age or older. MDD: The member is 18 years of age or older. Irritability associated with Autistic Disorder or Tourette's Disorder: The member is 6 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **OPSUMIT - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **OPSYNVI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member has a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **ORGOVYX - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agents. Pediatric members less than 18 years old.
Required Medical Information	Prostate Cancer: The member has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **ORSERDU - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Estrogen Receptor (ER)- positive Breast Cancer: The member has ER- positive, HER2-negative advanced or metastatic breast cancer AND the breast cancer has documented ESR1-mutation as determined by FDA approved test AND the member has progressive disease following at least one prior line endocrine therapy (e.g., fulvestrant, CDK 4/6 inhibitor) AND Orserdu (elacestrant) is given as single agent as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **OSPHENA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must be post-menopausal AND the member must have vulvar and/or vaginal atrophy AND one of the following: the member must have moderate to severe dyspareunia OR the member must have moderate to severe vaginal dryness.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# OTULFI - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis (SC formulation only): The member must have a diagnosis of moderate to severe chronic plaque psoriasis AND The member has had prior therapy or intolerance to one or more oral systemic tretaments (e.g. methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic arthritis (SC formulation only): The member must have a diagnosis of active psoriatic arthritis. Moderately to severely active Crohn's disease (IV and SC formulations). The member must have a diagnosis of moderately to severely active colitis (IV and SC formulations): The member must have a diagnosis of active ulcerative colitis (IV and SC formulations): The member must have a diagnosis of active ulcerative colitis (IV and SC formulations): The member must have a diagnosis of moderately to severely active ulcerative colitis.
Age Restriction	Moderate to severe chronic plaque psoriasis and psoriatic arthritis: The member must be 6 years of age or older. For all other indications: Must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# OZEMPIC - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member is using for weight loss.
Required Medical Information	Diabetes Mellitus. The member has a diagnosis of type 2 diabetes mellitus.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# paclitaxel protein-bound - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Breast Cancer. The member has a diagnosis of metastatic (Stage IV) or recurrent breast cancer. The member received prior therapy that included an anthracycline (unless contraindicated). The member has documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity premedications. Non-small Cell Lung Cancer (NSCLC). The member has a diagnosis of locally advanced, recurrent or metastatic NSCLC. Member has documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity reaction to conventional Taxol or Taxotere or the member has a documented contraindication to standard hypersensitivity premedications AND member has squamous histology where Abraxane will be given in combo with Keytruda and carboplatin as first line therapy OR member will be using Abraxane as monotherapy or in combo with carboplatin AND One of the following apply: will be using for first line therapy OR member will be using as subsequent therapy for EGFR mutation-positive tumors after prior therapy OR member will be using as subsequent therapy for ROS-1 positive disease after prior therapy OR member will be using as subsequent therapy and EGFR, ALK, BRAF V600E, and ROS-1 negative disease OR member has metastatic NSCLC, non- squamous histology with no EGFR or ALK genomic tumor aberrations AND Abraxane will be given combo with Tecentriq and carboplatin as first line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration

# paclitaxel protein-bound - VIAL (EA)

Other Criteria	Ovarian Cancer. The member has a diagnosis of epithelial ovarian cancer, fallopian tube cancer or primary peritoneal cancer. The member meets one of the following criteria: Progressive, stable or persistent disease on primary chemotherapy OR Recurrent disease. The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) or Taxotere (docetaxol) or the member has a documented contraindication to standard hypersensitivity premedications. Pancreatic Cancer: The member has a diagnosis of pancreatic cancer and Abraxane is being used in combination with gemcitabine as neoadjuvant therapy or The member has a diagnosis of metastatic pancreatic cancer AND The member will be using Abraxane in combination with gemcitabine. Melanoma: The member has a diagnosis of unresectable or metastatic melanoma AND The member will be using Abraxane (nab-paclitaxel) as second-line or subsequent therapy after progression on BRAF targeted therapy AND The member has documented hypersensitivity reaction to conventional Taxol (paclitaxel) or Taxotere (docetaxol) or the member has a documented contraindication to standard hypersensitivity premedications.
Part B Prerequisite	0

# PADCEV - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Bladder Cancer. The member has locally advanced or metastatic bladder cancer AND one of the following applies: The member will be using Padcev (enfortumab vedotin-ejfv) as monotherapy AND The member has received prior treatment with a platinum-containing chemotherapy AND The member has received previous treatment with a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor OR The member has previously received one or more prior lines of therapy AND The member is ineligible for cisplatin- containing chemotherapy* OR the member is receiving Padcev (enfortumab vedotin-ejfv) in combination with Keytruda (pembrolizumab) in the front-line setting. *Cisplatin-ineligible comorbidities may include the following: CCrCl less than 60 mL/min, PS greater than or equal to 2, hearing loss of greater than or equal to 25 decibels (dB) at two contiguous frequencies, grade greater than or equal to 2 peripheral neuropathy, or NYHA class greater than or equal to 3. Carboplatin may be substituted for cisplatin particularly in those patients with a CrCl less 60 mL/min.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# PANRETIN - GEL (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	AIDS-related Kaposi's sarcoma: The member has a diagnosis of AIDS- related Kaposi's sarcoma AND systemic therapy is not required.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# pazopanib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on previous pazopanib therapy.
Required Medical Information	Advanced Renal Cell Carcinoma RCC). The member has a diagnosis of advanced renal cell carcinoma (stage IV). First-line therapy as a single agent for relapsed or unresectable stage IV disease with predominant clear cell histology OR as subsequent therapy as a single agent for relapsed or unresectable stage IV disease with predominant clear cell histology in members who have progressed on prior first-line therapy.Soft Tissue Sarcoma. The member has a diagnosis of soft tissue sarcoma AND The member has progressed after prior chemotherapy. Thyroid Carcinoma: The member has a diagnosis of advanced or metastatic radio-iodine refractory follicular carcinoma, Hurthle cell carcinoma, papillary OR the member has a diagnosis of advanced medullary carcinoma and has disease progression on or intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). Ovarian Cancer. The member has a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer. Uterine Neoplasms. The member has a diagnosis of stage II, III, IV, or advanced metastatic uterine neoplasm sarcoma and disease is not suitable for primary surgery AND Votrient (pazopanib) will be used as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# PEGASYS - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Hepatitis B - Adults: The member must have a diagnosis of chronic hepatitis B AND The member must have compensated liver disease AND The member must have evidence of viral replication AND The member must have evidence of liver inflammation AND The member must have had prior therapy, contraindication, or intolerance with two of the following: Vemlidy, tenofovir disoproxil fumarate, or entecavir. Chronic Hepatitis B - Pediatrics: The member must have a diagnosis of chronic hepatitis B AND The member must be non-cirrhotic AND The member must be HBeAg-positive AND The member must have evidence of viral replication AND The member must have elevation in serum alanine aminotransferase (ALT) AND the member must have had prior therapy, contraindication, or intolerance with two of the following: Vemlidy, tenofovir disoproxil fumarate , or entecavir. Chronic Hepatitis C - Adults: The member must have a diagnosis of chronic hepatitis C AND HCV ribonucleic acid (RNA) level must be documented prior to therapy AND The member has compensated liver disease AND Pegasys (peginterferon alpha-2a) will be taken in combination with at least 1 other member has had previous treatment, contraindication, or intolerance to Epclusa.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 to 120 week treatment course depending on the disease state and/or genotype.
Other Criteria	Chronic Hepatitis C - Pediatrics: The member must have a diagnosis of chronic hepatitis C AND HCV ribonucleic acid (RNA) level must be documented prior to therapy AND The member has compensated liver disease AND Pegasys (peginterferon alpha-2a) will be taken in combination with ribavirin AND the member has had previous treatment, contraindication, or intolerance to Epclusa.
Part B Prerequisite	0

#### **PEMAZYRE - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experienced disease progression on Pemazyre (pemigatinib)
Required Medical Information	Cholangiocarcinoma: The member has unresectable locally advanced or metastatic cholangiocarcinoma and the disease is fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test and the member has received prior treatment AND Pemazyre (pemigatinib) is given as a single agent for subsequent therapy. Relapsed or refractory myeloid/lymphoid neoplasms: the member has a diagnosis of relapsed or refractory myeloid/lymphoid neoplasms (MLNs) AND MLNs documented as fibroblast growth factor receptor 1 (FGFR1) rearrangement.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	
Part B Prerequisite	0

# pemetrexed - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NSCLC (non-squamous): Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute. All other indications: Creatinine clearance (CrCl) less than 45 ml/minute.
Required Medical Information	Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0 -2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR Alimta is being used as a single agent for the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with Alimta OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration

## pemetrexed - VIAL (EA)

Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.
0
Criteria Details
NSCLC (non-squamous): Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute. All other indications: Creatinine clearance (CrCl) less than 45 ml/minute.

## pemetrexed - VIAL (EA)

Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0 -2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR Alimta is being used as a single agent of the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with Alimta OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Licensed Practitioner
Plan year duration

## pemetrexed - VIAL (EA)

Other Criteria	Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.
Part B Prerequisite	0
	1

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NSCLC (non-squamous): Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute. All other indications: Creatinine clearance (CrCl) less than 45 ml/minute.
Required Medical Information	Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0 -2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR Alimta is being used as a single agent after prior chemotherapy. Alimta is being used as a single agent for the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with Alimta OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration

### pemetrexed disodium - VIAL (EA)

Other Criteria	Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.
Part B Prerequisite	0

## PEMRYDI RTU - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	NSCLC (non-squamous): Squamous cell non-small cell lung cancer. Creatinine clearance (CrCl) less than 45 ml/minute. All other indications: Creatinine clearance (CrCl) less than 45 ml/minute.
Required Medical Information	Non-Small Cell Lung Cancer (Nonsquamous). Diagnosis of nonsquamous NSCLC that is locally advanced or metastatic AND EGFR, ALK, ROS1 BRAF negative and PD-L1 less than 1% AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the initial treatment in members with a performance status (PS) 0-2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis or as a single agent in PS 2 OR If EGFR, ALK, ROS1, BRAF positive and PD-L1 greater than or equal to 1% and after prior therapy AND one of the following applies: Alimta is being used in combination with cisplatin or carboplatin therapy for the subsequent therapy in members with a performance status (PS) 0 -2 or Alimta is being used in cisplatin or carboplatin-based regimens in combination with bevacizumab product in members with PS 0-1 and no history of hemoptysis as subsequent therapy or as a single agent in PS 2 as subsequent therapy. OR Alimta is being used as a single agent after prior chemotherapy. Alimta is being used as a single agent of the maintenance treatment of members whose disease has not progressed after four cycles of platinum-based first-line chemotherapy OR As a single agent for recurrence or metastasis in members who achieved tumor response or stable disease following first-line chemotherapy with Alimta OR in combination with Keytruda and carboplatin or cisplatin as first line therapy for nonsquamous metastatic NSCLC followed by maintenance Keytruda in combination with pemetrexed OR in combination with cisplatin used as neoadjuvant or adjuvant chemotherapy OR Concurrent chemoradiation in combination with carboplatin or cisplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration

## PEMRYDI RTU - VIAL (ML)

Other Criteria	Malignant Pleural Mesothelioma. Diagnosis of malignant pleural mesothelioma AND must be using pemetrexed as induction therapy in combination with cisplatin or carboplatin for medically operable clinical stage I-III OR must be using pemetrexed as a single agent or in combination with cisplatin or carboplatin OR is using pemetrexed as second-line as a single agent if not administered first-line. OR pemetrexed is being used in combination with bevacizumab product and cisplatin. Bladder Cancer: The member must have a diagnosis of metastatic bladder cancer AND pemetrexed is being used as second-line or subsequent therapy as a single agent for metastatic disease. Cervical Cancer. Diagnosis of cervical cancer AND pemetrexed is being used as a second-line or subsequent therapy as a single agent for local/regional recurrence or distant metastases. Ovarian Cancer. Diagnosis of Ovarian Cancer, or Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer AND pemetrexed is being used as a single agent for persistent disease or recurrence therapy. Thymic Malignancy. Diagnosis of thymic malignancy AND pemetrexed is being used as second-line therapy as a single agent.
Part B Prerequisite	0

### perampanel - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: The member has a diagnosis of partial- onset (focal) seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate). Adjunctive treatment of generalized tonic-clonic seizures: The member has a diagnosis of generalized tonic-clonic seizures AND Member will use Fycompa (perampanel) in combination with at least one other drug for controlling seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling generalized tonic-clonic seizures (e.g. lamotrigine, topiramate, carbamazepine, gabapentin, divalproex).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## PERJETA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member exceeds a total treatment of 52 weeks or 18 treatment cycles (applicable to neoadjuvant and/or adjuvant treatment).
Required Medical Information	Metastatic Breast Cancer. The member has a diagnosis of metastatic breast cancer and HER2 (human epidermal growth factor receptor2) positive disease (e.g., defined as IHC 3+ or IHC2+/ISH positive) AND one of the following applies: will be receiving Perjeta (pertuzumab) in combination with trastuzumab product and docetaxel or paclitaxel and has not received prior anti-HER2 therapy or chemotherapy for metastatic disease OR The member will be receiving Perjeta (pertuzumab) in combination with a trastuzumab product with or without cytotoxic therapy as second or subsequent line therapy in members previously treated with chemotherapy and a trastuzumab product in the absence of prior Perjeta (pertuzumab). Early Stage Breast Cancer. The member has a diagnosis of locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) and HER2 positive disease (e.g., defined as IHC 3+ or IHC2+/ISH positive) AND Perjeta (pertuzumab) will be used as neoadjuvant treatment as part of a complete treatment regimen and one of the following applies: in combination with trastuzumab product and docetaxel or paclitaxel (after completion of combination of doxorubicin plus cyclophosphamide regimen) or in combination with TCH (docetaxel, carboplatin, and trastuzumab product) OR The member has a diagnosis of early stage HER2 (e.g., defined as IHC 3+ or IHC2+/ISH positive) positive breast cancer at high risk of recurrence (e.g., node positive disease, hormone receptor negative, T2 non-metastatic disease) AND Perjeta (pertuzumab) will be used as adjuvant therapy and one of the following applies: combination with trastuzumab product and paclitaxel or docetaxel or docetaxel (following doxorubicin plus cyclophosphamide regimen) or docetaxel (store carboplatin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## pimecrolimus - CREAM (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Must have a diagnosis of atopic dermatitis and have had previous treatment with one of the following topical generic products: triamcinolone 0.025%, 0.1%, 0.5%, mometasone, betamethasone dipropionate.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **PIQRAY - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members have severe hypersensitivity to Piqray (alpelisib). Members has experienced disease progression on PIK3CA inhibitors (e.g., alpelisib).
Required Medical Information	Breast Cancer: The member has a diagnosis of advanced or metastatic hormone receptor positive, human epidermal growth factor receptor 2 (HER 2) negative breast cancer and PIK3CA mutated as detected by FDA approved test AND the member has experienced disease progression on or after endocrine based therapy (e.g., aromatase inhibitor, cyclin-dependent kinase (CDK) 4/6 inhibitor) AND Piqray (alpelisib) will be given in combination with fulvestrant as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## pirfenidone - TABLET

	j
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Idiopathic Pulmonary Fibrosis (IPF):The member meets ALL of the following criteria: Documentation of Pulmonary Fibrosis by one of the following: computed tomography (CT) scan that is indicative of usual interstitial pneumonia (UIP) OR surgical lung biopsy AND Has not had clinically significant environmental exposure or explanation for pulmonary fibrosis or interstitial lung disease (e.g. drugs, asbestos, beryllium, radiation, and domestic birds, radiation, sarcoidosis, hypersensitivity pneumonitis, bronchiolitis, obliterans organizing pneumonia, human immunodeficiency virus (HIV), viral hepatitis, or cancer).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## POLIVY - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Diffuse large B-cell lymphoma - relapsed/refractory: Member has experienced disease progression on Polivy (polatuzumab vedotin-piiq). The member has active central nervous system lymphoma. The member has transformation from indolent lymphoma (e.g. follicular lymphoma) info diffuse large B-cell lymphoma. The member has received prior allogeneic hematopoietic stem cell transplant (HSCT). Diffuse large B- cell lymphoma - treatment-naive: The member has active central nervous system lymphoma. The member has transformation from indolent lymphoma (e.g. follicular lymphoma) info diffuse large B-cell lymphoma.
Required Medical Information	Diffuse large B-cell lymphoma - relapsed/refractory: the member has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma AND the member has received at least two prior lines of therapy AND the member will be using in combination with bendamustine and a rituximab product. Diffuse large B-cell lymphoma - treatment-naive: the member has a diagnosis of diffuse large B-cell lymphoma, not otherwise specified or high-grade B-cell lymphoma AND the member has not received previous treatment AND the member has a disease with a International Prognostic Index score of 2 or greater AND the member has stage II with extensive mesenteric disease or a higher stage (i.e. stage III/IV) AND the member will be using Polivy (polatuzumab vedotin-piiq) in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHOP).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **POMALYST - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Pomalyst (pomalidomide).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of Multiple Myeloma AND The member has received at least two previous therapies AND The member has demonstrated disease progression while on Revlimid (lenalidomide) OR Thalomid (thalidomide) AND The member demonstrated disease progression while on a protease inhibitor (e.g. bortezomib, carflizomib) AND The member demonstrated disease progression on or within 60 days of completion of the last therapy regimen [does not apply to requests for combination with Darzalex (daratumumab) plus dexamethasone or elotuzumab plus dexamethasone or Sarclisa (isatuximab) plus dexamethasone] AND The member will be using Pomalyst in one of the following regimens: in combination with dexamethasone and daratumumab, with dexamethasone and elotuzumab, with dexamethasone and ixazomib, with dexamethasone and cyclophosphamide, with dexamethasone, with dexamethasone and Sarclisa (isatuximab), dexamethasone and Xpovio (selinexor), or as a single agent (Omission of corticosteroid from regimen is allowed if intolerance/contraindication). Kaposi Sarcoma: The member has a diagnosis of AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy OR The member has a diagnosis of Kaposi sarcoma that is HIV-negative.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

## PORTRAZZA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Portrazza (necitumumab).
Required Medical Information	Non-Small Cell Lung Cancer: The member has a diagnosis of metastatic squamous non-small cell lung cancer AND The member will be initially using Portrazza (necitumumab) in combination with gemcitabine and cisplatin AND The member will be using Portrazza (necitumumab) as first-line treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## posaconazole - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Prophylaxis against Invasive Aspergillus and Candida Infections. The member must be using it for prophylaxis against invasive Aspergillus or Candida infections, and The member must be severely immunocompromised (such as hematopoietic stem cell transplant recipient with graft-vs-host disease, or neutropenic patients with acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS). Treatment of invasive Aspergillus or fungal infections caused by Fusarium and/or Zygomycetes. The member must have documentation for treatment of invasive Aspergillus or fungal infections caused by Fusarium and/or Zygomycetes, and The member must have documented resistant strains of or clinically refractory to standard antifungal agents (e.g. voriconazole, itraconazole) or those who can not receive other antifungal agents due to potential toxicities, intolerance, or contraindications. Treatment of Esophageal Candidiasis. The member must have a diagnosis for esophageal candidiasis and The member has a documented inadequate response/refractory or intolerant to itraconazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## POTELIGEO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member has experienced disease progression while on or following Poteligeo (mogamulizumab-kpkc).
Required Medical Information	Mycosis fungoides or Sézary syndrome: The member has a diagnosis of mycosis fungoides or Sézary syndrome AND The member has relapsed or refractory disease AND The member will be using Poteligeo (mogamulizumab-kpkc) as the sole systemic therapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	NA
Part B Prerequisite	0

## pralatrexate - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on pralatrexate.
Required Medical Information	Peripheral T-cell Lymphoma(PTCL):relapsed or refractory. Pralatrexate is being used to treat relapsed or refractory peripheral T-cell lymphoma (PTCL) (eg peripheral T-cell lymphoma, not otherwise specified: angioimmunoblastic T-cell lymphoma, anaplastic large cell lymphoma or enteropathy-associated T-cell lymphoma.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **PREVYMIS - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Prophylaxis (PPX) of CMV Infection and Disease in CMV Seropositive Recipients [R+] of an Allogenic Hematopoietic Stem Cell Transplant (HSCT). Member must have received an allogeneic hematopoietic stem cell transplant. Member must be CMV-seropositive [R+]. Member must weigh at least 6 kg. Prevymis (letermovir) must be initiated within 28 days post-transplant. Prophylaxis (PPX) of CMV disease in kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]). Member must have received a kidney transplant AND Member must be CMV-seropositive (R-) AND Member must have received a kidney from a CMV-seropositive (D+) donor AND Member must weigh at least 40 kg AND Member must have a medical reason as to why valganciclovir therapy cannot be started or continued (e.g., breakthrough CMV infection, adverse effects leading to discontinuation of valganciclovir).
Age Restriction	Prophylaxis of CMV Infection and Disease in CMV Seropositive Recipients [R+] of an Allogeneic Hematopoietic Stem Cell Transplant (HSCT): The member must be at least 6 months of age or older. Prophylaxis of CMV disease in kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]): The member must be at least 12 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 Months Duration
Other Criteria	
Part B Prerequisite	0

#### **PROMACTA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	ITP members with previous documented failure of eltrombopag.
Required Medical Information	Chronic Idiopathic Thrombocytopenic Purpura. Initial Approval: The member has a diagnosis of relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) AND The member has a platelet count of less than 50 x 109/L. The member has had an insufficient response or is intolerant to corticosteroids OR The member has had a splenectomy with an inadequate response AND had an insufficient response or is intolerant to post-splenectomy corticosteroids. Reauthorizations. The member has a platelet count of less than 400 x 109/L. Thrombocytopenia in Patients with Hepatitis C Infection: Initial Approval: The member has a diagnosis of chronic hepatitis C. The member has a platelet count of less than 75 x 109/L. The degree of thrombocytopenia is preventing the initiation of interferon therapy OR limits the ability to maintain optimal interferon based therapy. Reauthorization: The member has a platelet count of less than 400 x 109/L AND The member continues to receive interferon based therapy. Aplastic Anemia: Initial Approval: The member has a diagnosis of aplastic anemia AND The member will receive Promacta (eltrombopag) in combination with immunosuppressive therapy (e.g. cyclosporine, antithymocyte immune globulin) for first-line treatment of severe aplastic anemia OR Promacta (eltrombopag) is being used for the treatment of refractory severe aplastic anemia in members with an insufficient response to immunosuppressive therapy (e.g. cyclosporine, antithymocyte immune globulin). Reauthorization: The member has a platelet count of less than 400 x 109/L.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **QINLOCK - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experiences disease progression on Qinlock (ripretinib).
Required Medical Information	Gastrointestinal Stromal Tumor (GIST): The member has a diagnosis of advanced GIST AND The member has received prior therapy with three or more kinase inhibitors, including imatinib AND Qinlock (ripretinib) is being used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA
Part B Prerequisite	0

## quinine sulfate - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prolongation of QT interval. Myasthenia gravis. Optic neuritis.
Required Medical Information	Plasmodium Falciparum Malaria: Diagnosis of uncomplicated chloroquine-resistant Plasmodium falciparum malaria.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **QULIPTA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Migraine Prevention: Will be utilizing Qulipta (atogepant) for the preventative treatment of migraines.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### RADICAVA ORS - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Amyotrophic Lateral Sclerosis (ALS): Member has a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) as determined by a provider who specializes in the treatment of ALS (e.g.neurologist, neuromuscular specialist) AND Member has a baseline score of 2 points or greater for each individual item on the ALS Functional Rating Scale- Revised (ALSFRS-R) AND Member is able to independently perform all or some activities of daily living (ADLs) when therapy is started AND Member has a disease duration of 2 years or less when therapy is started AND Member is also being treated with riluzole OR has previously tried and cannot use riluzole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# RADICAVA ORS STARTER KIT SUSP - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Amyotrophic Lateral Sclerosis (ALS): Member has a diagnosis of definite or probable amyotrophic lateral sclerosis (ALS) as determined by a provider who specializes in the treatment of ALS (e.g.neurologist, neuromuscular specialist) AND Member has a baseline score of 2 points or greater for each individual item on the ALS Functional Rating Scale- Revised (ALSFRS-R) AND Member is able to independently perform all or some activities of daily living (ADLs) when therapy is started AND Member has a disease duration of 2 years or less when therapy is started AND Member is also being treated with riluzole OR has previously tried and cannot use riluzole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **REPATHA PUSHTRONEX - WEARABLE INJECTOR**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Diagnosis of primary hyperlipidemia (Note: includes heterozygous familial hypercholesterolemia [HeFH], pure hypercholesterolemia, and mixed hyperlipidemia) AND Repatha (evolocumab) is used as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDL-C reduction OR The member is determined to have statin-associated muscle symptoms (SAMs) and SAMs symptoms included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength AND attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects.
Age Restriction	Member must be 10 years of age or older for diagnosis of Primary Hyperlipidemia. Member must be 18 years of age or older for Clinical Atherosclerotic Cardiovascular Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### **REPATHA PUSHTRONEX - WEARABLE INJECTOR**

Other Criteria	Clinical Atherosclerotic Cardiovascular Disease (ASCVD): The member must have documentation of an ASCVD (e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin) AND Repatha (evolocumab) is used as adjunctive therapy in members taking maximally tolerated high-intensity statin therapy (e.g. atorvastatin or rosuvastatin) and have failed to achieve goal LDL-C OR the member is determined to have statin-associated muscle symptoms (SAMs) and SAMs symptoms included rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength and attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects. Homozygous Familial Hypercholesterolemia (HoFH): The member must have a diagnosis of definite HoFH as defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untreated LDL-C greater than 400 mg/dL (10.3 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or treated non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) with at least one of the following: Cutaneous or tendon xanthoma before age 10 years OR Elevated LDL cholesterol levels before lipid-lowering consistent with HFH in both parents [untreated total cholesterol greater than 250 mg/dL (6.5 mmol/L) or untreated LDL-C greater than 190 mg/dL (4.9 mmol/L)]. Repatha (evolocumab) is used as adjunctive therapy to other LDL-lowering therapies (e.g. statins, ezetimibe) in members that have failed to achieve goal LDL-C reduction.
Part B Prerequisite	0

## REPATHA SURECLICK - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Diagnosis of primary hyperlipidemia (Note: includes heterozygous familial hypercholesterolemia [HeFH], pure hypercholesterolemia, and mixed hyperlipidemia) AND Repatha (evolocumab) is used as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDL-C reduction OR The member is determined to have statin-associated muscle symptoms (SAMs) and SAMs symptoms included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength AND attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects.
Age Restriction	Member must be 10 years of age or older for diagnosis of Primary Hyperlipidemia. Member must be 18 years of age or older for Clinical Atherosclerotic Cardiovascular Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## REPATHA SURECLICK - PEN INJECTOR (ML)

Other Criteria	Clinical Atherosclerotic Cardiovascular Disease (ASCVD): The member must have documentation of an ASCVD (e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin) AND Repatha (evolocumab) is used as adjunctive therapy in members taking maximally tolerated high-intensity statin therapy (e.g. atorvastatin or rosuvastatin) and have failed to achieve goal LDL-C OR the member is determined to have statin-associated muscle symptoms (SAMs) and SAMs symptoms included rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength and attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects. Homozygous Familial Hypercholesterolemia (HoFH): The member must have a diagnosis of definite HoFH as defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untreated LDL-C greater than 400 mg/dL ( 10.3 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or treated non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) with at least one of the following: Cutaneous or tendon xanthoma before age 10 years OR Elevated LDL cholesterol levels before lipid-lowering consistent with HeFH in both parents [untreated total cholesterol greater than 250 mg/dL (6.5 mmol/L) or untreated LDL-C greater than 190 mg/dL (4.9 mmol/L)]. Repatha (evolocumab) is used as adjunctive therapy to other LDL-lowering therapies (e.g. statins, ezetimibe) in members that have failed to achieve goal LDL-C reduction.
Part B Prerequisite	0

## REPATHA SYRINGE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Diagnosis of primary hyperlipidemia (Note: includes heterozygous familial hypercholesterolemia [HeFH], pure hypercholesterolemia, and mixed hyperlipidemia) AND Repatha (evolocumab) is used as adjunctive therapy to maximally tolerated high intensity statin therapy (e.g. atorvastatin or rosuvastatin) in members that have failed to achieve goal LDL-C reduction OR The member is determined to have statin-associated muscle symptoms (SAMs) and SAMs symptoms included rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength AND attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects.
Age Restriction	Member must be 10 years of age or older for diagnosis of Primary Hyperlipidemia. Member must be 18 years of age or older for Clinical Atherosclerotic Cardiovascular Disease.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## REPATHA SYRINGE - SYRINGE (ML)

Other Criteria	Clinical Atherosclerotic Cardiovascular Disease (ASCVD): The member must have documentation of an ASCVD (e.g. acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack or peripheral arterial disease, all of presumed atherosclerotic origin) AND Repatha (evolocumab) is used as adjunctive therapy in members taking maximally tolerated high-intensity statin therapy (e.g. atorvastatin or rosuvastatin) and have failed to achieve goal LDL-C OR the member is determined to have statin-associated muscle symptoms (SAMs) and SAMs symptoms included rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMs despite both lowering of statin strength and attempting a different statin OR provider attestation that statin use has been tried and failed and is not clinically appropriate due to intolerable adverse effects. Homozygous Familial Hypercholesterolemia (HoFH): The member must have a diagnosis of definite HoFH as defined by at least one of the following: Genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or ARH adaptor protein gene locus OR an untreated LDL-C greater than 400 mg/dL (10.3 mmol/L) or treated LDL-C greater than or equal to 300 mg/dL (7.76 mmol/L) or treated non-HDL cholesterol greater than or equal to 330 mg/dL (8.5 mmol/L) with at least one of the following: Cutaneous or tendon xanthoma before age 10 years OR Elevated LDL cholesterol levels before lipid-lowering consistent with HeFH in both parents [untreated total cholesterol greater than 250 mg/dL (6.5 mmol/L) or untreated LDL-C greater than 190 mg/dL (4.9 mmol/L)]. Repatha (evolocumab) is used as adjunctive therapy to other LDL-lowering therapies (e.g. statins, ezetimibe) in members that have failed to achieve goal LDL-C reduction.
Part B Prerequisite	0

## RETACRIT - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Anemia of CKD: Diagnosis of anemia associated with chronic kidney disease. Hgb level less than 10.0 g/dL or HCT less than 30- within last 4 weeks. Continue Therapy: Current- within last 4 weeks Hgb level less than 11 g/dL OR documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Anemia in Zidovudine-treated HIV-infected: Diagnosed with HIV (and AZT induced anemia) and receiving zidovudine treatment corresponding with HAART. Endogenous serum erythropoietin levels less than or equal to 500 mUnits/mL. The total zidovudine dose must not exceed 4200mg/wk. Must have Hgb level less than or equal to 10.0 g/dL or HCT less than 30-within the last four weeks. Continue Therapy: Zidovudine dose must not exceed 4200mg/wk. Must meet one of the following criteria: Current-within last 4 weeks Hgb level less than 12.0 g/dL OR Documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Goal Hgb level should not exceed 12.0g/dL. Anemia in Chemotherapy Treated Cancer - first 4 weeks. Diagnosis with a non-myeloid, non-erythroid malignancy. Must be receiving concurrent chemotherapy treatment for incurable disease with palliative intent. Must have Hgb level less than 10.0 g/dL or HCT less than 30-within last 4 weeks. Maint. Phase after first 4 weeks: Member has responded to therapy, defined as one or more of the following: increase in hemoglobin of at least 1 g/dL OR An increase in hemoglobin to greater than or equal to 10 g/dL OR a decrease in red blood cell (RBC) transfusion requirements OR prescriber determines to continue therapy. Continued dosing is needed to maintain the lowest hemoglobin level sufficient to avoid RBC transfusion.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial: Plan year duration. Reauth: Plan year duration.

#### **RETACRIT - VIAL (ML)**

#### **Other Criteria**

Anemia in Surgery Members: Must be scheduled to undergo elective, noncardiac, nonvascular surgery. Must have Hab level of greater than 10 g/dL and less than or equal 13 g/dL (within last 4 weeks). Anemia in Myelodysplastic Syndromes: Diagnosis of symptomatic anemia associated with MDS. Must have a serum erythropoietin level less than or equal to 500 mUnits/mL (unlikely to respond to ESA therapy if erythropoietin level greater than 500mUnits/ml). Must have Hgb level less than 12 g/dL or HCT less than 30 (within last 4 weeks). Continue Therapy: The member has responded to therapy, defined as one or more of the following: An increase in hemoglobin of at least 1.5 g/dL OR An increase in hemoglobin to greater than or equal to 10 g/dL OR a decrease in red blood cell (RBC) transfusion requirements, OR prescriber determines to continue therapy. Continued dosing is needed to maintain the lowest hemoglobin level (not to exceed 12 g/dL) sufficient to avoid RBC transfusion. Anemia associated with Management of Hepatitis C. Diagnosis of anemia in management of chronic Hepatitis C. Receiving combination treatment for chronic Hepatitis C with interferon (IFN)/ribavirin (RBV) or pegylated (PEG) IFN/RBV. Must have Hgb level less than or equal to 12.0 gm/dL or HCT less than 30 during combination therapy as defined above (within the last 4 weeks). Continue Therapy: Must be receiving combination treatment for chronic Hepatitis C with interferon (IFN)/ribavirin (RBV) or pegylated (PEG) IFN/RBV. Must have been able to maintain previous ribavirin dosing without dose reduction due to symptomatic anemia. Must meet one of the following criteria: Current (within the last 4 weeks) Hgb level less than 12.0g/dL OR Documented dose adjustment of therapy with corresponding documented Hgb levels to indicate maintenance therapy. Goal Hgb level should not exceed 12.0g/dL. Anemia associated with Rheumatoid Arthritis (RA) Treatment. Diagnosis of anemia associated with pharmaceutical treatment of RA. Receiving active therapy known to cause anemia. Must have Hgb level less than 10 g/dL or HCT less than 30 (within the last 4 weeks). Continue Therapy: Receiving active RA pharmaceutical treatment. Current (within the last 4 weeks) Hgb less than 11 g/dL. For listed indications: Prior to initiation of therapy, other causes of anemia including iron, B-12, folate deficiencies, hemolysis, and bleeding have been ruled out. Prior to initiation of therapy, the member's iron scores should be evaluated. Transferrin saturation should be at least 20% OR ferritin at least 100 ng/mL within the last 4 months (applies to most recent result). Continuation of therapy requires documented Transferrin saturation of at least 20% OR ferritin of at least 100 ng/ mL within the last 4 months for all indications (applies to most recent result). 0 Part B Prerequisite

#### **RETEVMO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Retevmo
Required Medical Information	Pending CMS Review
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **REVUFORJ - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following Revuforj (revumenib).
Required Medical Information	Acute Leukemia: The member has a diagnosis of acute leukemia AND the member has relapsed or refractory disease AND the member has documented lysine methyltransferase 2A (KMT2A) mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **REXULTI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Major depressive disorder: The member has a clinical diagnosis of major depressive disorder (MDD) AND The member must have documentation of prior therapy, intolerance, or contraindication to at least one generic oral atypical antipsychotic therapy AND Rexulti must be used as adjunctive treatment to antidepressant therapy and not as monotherapy. Schizophrenia: The member must have clinically diagnosed schizophrenia AND The member must have documentation of prior therapy, intolerance, or contraindication to one generic oral atypical antipsychotic therapies. Agitation Associated with Dementia Due to Alzheimer's Disease: The member must have clinically diagnosed agitation associated with dementia due to Alzheimer's disease AND Rexulti (brexpiprazole) will not be used as a needed (prn) treatment for agitation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **REZLIDHIA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on or following Rezlidhia (olutasidenib).
Required Medical Information	Acute Myeloid Leukemia - Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member has a documented IDH1 mutation AND The member will be using Rezlidhia (olutasidenib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

# RIABNI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Chronic Lymphocytic Leukemia: High dose CLL therapies (doses greater than 500mg/m <sup>2</sup> ). The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia. Non-Hodgkin's Lymphoma (CD-20 positive/B-cell): The member will be using rituximab as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma). Waldenstrom's Macroglobulinemia: The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Required Medical Information	For requests for Rituxan or Truxima: member must have intolerance or contraindication with Ruxience or Riabni and meet the criteria below. Chronic Lymphocytic Leukemia. The member has a diagnosis of CLL. Non-Hodgkin's Lymphoma (CD-20 positive/B-Cell). The member has a diagnosis of CD-20 positive/B-cell Non-Hodgkin's lymphoma. Hodgkin's Disease (Hodgkin's Lymphoma). The member has a diagnosis of Hodgkin's Disease. The member will be using rituximab product for primary treatment or for relapsed or progressive disease AND disease has confirmed CD20 positivity. Rheumatoid Arthritis. The member has a diagnosis of moderately- to severely-active rheumatoid arthritis. The member has had previous treatment with, contraindication, or intolerance with one of the following: Remicade, Inflectra, infliximab, or Simponi Aria* (previous treatment with Simponi Aria applies to medical benefit requests only). The member must be on concomitant treatment with methotrexate during rituximab product therapy, unless contraindicated or intolerant to methotrexate.
Age Restriction	Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

### RIABNI - VIAL (ML)

Other Criteria	Waldenstram's macroglobulinemia. The member must have a diagnosis of Waldenstram's macroglobulinemia. Post-transplant lymphoproliferative disorder. The member has a diagnosis of Post- transplant Lymphoproliferative disease. Immune or Idiopathic Thrombocytopenic Purpura. The member must have a diagnosis of refractory primary immune or idiopathic thrombocytopenic purpura. Member has not had a splenectomy, but has had an insufficient response or is intolerant to corticosteroids, AND immunoglobulins (IVIG), OR has had a splenectomy with an inadequate response or is intolerant to procedure AND had an insufficient response or is intolerant to procedure AND had an insufficient response or is intolerant to post- splenectomy corticosteroids. Refractory response is characterized as EITHER: Platelet count less than 25,000/microliter OR Active bleeding due to inadequate platelet function. The member must have had an inadequate response to post-splenectomy corticosteroid therapy for four consecutive weeks within the last three months. Diagnosis of Wegener's Granulomatosis OR Microscopic Polyangiitis. Must be taking rituximab product in combination with glucocorticoids. Pemphigus Vulgaris (PV). The member must have a diagnosis of moderate to severe Pemphigus Vulgaris.
Part B Prerequisite	0

### RINVOQ - TABLET, EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Rheumatoid Arthritis: The member has a diagnosis of moderate to severely active rheumatoid arthritis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adbm, adalimumab-adaz). Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adbm, adalimumab-adbm, adalimumab-adaz). Atopic Dermatitis: The member has a diagnosis of moderate to severe atopic dermatitis AND the member has had prior therapy, contraindication or intolerance with at least one other systemic therapy. Ulcerative Colitis: the member has a diagnosis of moderately to severely active ulcerative colitis AND the member has had prior therapy, contraindication, or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adaz). Ankylosing Spondylitis: the member has a diagnosis of active ankylosing spondylitis: the member has had prior therapy, contraindication or intolerance with one or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adbm, adalimumab-adaz). Non-radiographic Axial Spondylarthritis: the member has a diagnosis of non-radiographic axial spondylarthritis with signs of inflammation AND the member has had prior therapy, contraindication, or intolerance to one or more TNF blockers (e.g. Humira, adalimumab-adaz). Crohn's Disease: the member has a diagnosis of moderately to severely active crohn's disease AND the member has had prior therapy, contraindication, or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adaz). Crohn's Disease: the member has a diagnosis of moderately to severely active crohn's disease AND the member has had prior therapy, contraindication, or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adaz).
Age Restriction	RA, UC, ankylosing spondylitis, Non-radiographic axial spondylarthritis, Giant Cell Arteritis and Crohn's Disease: The member is 18 years of age or older. Atopic Dermatitis: the member is 12 years of age or older. Psoriatic arthritis and polyarticular juvenile idiopathic arthritis: the member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

#### **RINVOQ - TABLET, EXTENDED RELEASE 24 HR**

Other Criteria	Polyarticular Juvenile Idiopathic Arthritis: The member has a diagnosis of active polyarticular juvenile idiopathic arthrits AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adbm, adalimumab-adaz). Giant Cell Arteritis: the member has a diagnosis of giant cell arteritis.
Part B Prerequisite	0

# RINVOQ LQ - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab- adbm, adalimumab-adaz). Polyarticular Juvenile Idiopathic Arthritis: The member has a diagnosis of active polyarticular juvenile idiopathic arthritis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab- adalimumab-adaz).
Age Restriction	The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# ROMIDEPSIN - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on romidepsin.
Required Medical Information	Cutaneous T-cell Lymphoma (CTCL). Istodax (romidepsin) is being used to treat cutaneous T-cell lymphoma AND one of the following applies: the member will be using Istodax (romidepsin) as primary biologic systemic therapy OR the member has received at least one prior therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **ROMVIMZA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Symptomatic Tenosynovial Giant Cell Tumor: Member has symptomatic tenosynovial giant cell tumor (TGCT) AND Surgical resection will potentially cause worsening functional limitation or severe morbidity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### ROZLYTREK - PELLETS IN PACKET (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Non-Small Cell Lung Cancer (NSCLC): The member has a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) AND the member has disease which is ROS1-positive. Solid Tumors: the member has a diagnosis of solid tumors which are metastatic OR The member is not a candidate for surgical resection AND The member has a documented neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation AND The member's disease has progressed following treatment or does not have satisfactory alternative therapy options.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **RUBRACA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following PARP inhibitor therapy [e.g., Rubraca (rucaparib), Lynparza (olaparib), Zejula(niraparib)].
Required Medical Information	Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer Maintenance Therapy: The member has a diagnosis of epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND The member has deleterious BRCA mutation (germline and/or somatic) AND The member is in complete or partial response to their last platinum regimen AND The member will utilize Rubraca (rucaparib) as monotherapy* AND *Discontinue Bevacizumab product before initiating maintenance therapy with Rubraca. Metastatic Castration-Resistant Prostate Cancer: The member has a diagnosis metastatic castration-resistant prostate cancer (mCRPC) AND The member has documented deleterious BRCA mutation (germline and/or somatic) AND The member has had prior treatment with androgen receptor-directed therapy (e.g. abiraterone, Xtandi, Erleada, or Nubeqa) and a taxane-based chemotherapy (e.g. docetaxel) AND The member will use Rubraca (rucaparib) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or concurrent GnRH analog).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### rufinamide - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Patients with familial short QT syndrome.
Required Medical Information	Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS) AND Banzel (rufinamide) will be used in combination with at least one other drug for controlling seizures AND The member has been unable to achieve seizure control with at least one other drug used for the adjunctive treatment of Lennox-Gastaut syndrome (e.g., lamotrigine, topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# RUXIENCE - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Chronic Lymphocytic Leukemia: High dose CLL therapies (doses greater than 500mg/m <sup>2</sup> ). The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia. Non-Hodgkin's Lymphoma (CD-20 positive/B-cell): The member will be using rituximab as maintenance therapy for diffuse large B cell lymphoma (DLBCL). The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma). Waldenstrom's Macroglobulinemia: The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkins lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Required Medical Information	For requests for Rituxan or Truxima: member must have intolerance or contraindication with Ruxience or Riabni and meet the criteria below. Chronic Lymphocytic Leukemia. The member has a diagnosis of CLL. Non-Hodgkin's Lymphoma (CD-20 positive/B-Cell). The member has a diagnosis of CD-20 positive/B-cell Non-Hodgkin's lymphoma. Hodgkin's Disease (Hodgkin's Lymphoma). The member has a diagnosis of Hodgkin's Disease. The member will be using rituximab product for primary treatment or for relapsed or progressive disease AND disease has confirmed CD20 positivity. Rheumatoid Arthritis. The member has a diagnosis of moderately- to severely-active rheumatoid arthritis. The member has had previous treatment with, contraindication, or intolerance with one of the following: Remicade, Inflectra, infliximab, or Simponi Aria* (previous treatment with Simponi Aria applies to medical benefit requests only). The member must be on concomitant treatment with methotrexate during rituximab product therapy, unless contraindicated or intolerant to methotrexate.
Age Restriction	Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA): The member is 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

# RUXIENCE - VIAL (ML)

Other Criteria	<ul> <li>Waldenstram's macroglobulinemia. The member must have a diagnosis of Waldenstram's macroglobulinemia. Post-transplant</li> <li>lymphoproliferative disorder. The member has a diagnosis of Post-transplant Lymphoproliferative disease. Immune or Idiopathic</li> <li>Thrombocytopenic Purpura. The member must have a diagnosis of refractory primary immune or idiopathic thrombocytopenic purpura.</li> <li>Member has not had a splenectomy, but has had an insufficient response or is intolerant to corticosteroids, AND immunoglobulins (IVIG), OR has had a splenectomy with an inadequate response or is intolerant to post-splenectomy corticosteroids. Refractory response is characterized as EITHER: Platelet count less than 25,000/microliter OR Active bleeding due to inadequate platelet function. The member must have had an inadequate response to post-splenectomy corticosteroid therapy for four consecutive weeks within the last three months. Diagnosis of Wegener's Granulomatosis OR Microscopic Polyangiitis. Must be taking rituximab product in combination with glucocorticoids. Pemphigus Vulgaris (PV). The member must have a diagnosis of moderate to severe Pemphigus Vulgaris.</li> </ul>
Part B	0

#### **RYBELSUS - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member is using for weight loss.
Required Medical Information	Diabetes Mellitus. The member has a diagnosis of type 2 diabetes mellitus.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### RYBREVANT - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who have disease progression on Rybrevant (amivantamab) (does not apply to NSCLC EGFR Exon 19 Deletion or Exon 21 L858R Mutated [Lazcluze (lazertinib) Combination]).
Required Medical Information	Non-small cell lung cancer (NSCLC) [Monotherapy]: The member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) and all the following criteria applies: The NSCLC has documented epidermal growth factor receptor (EGFR) exon 20 insertion mutations (e.g. as detected by a FDA-approved test) AND the member has documented disease progression on prior platinum-based chemotherapy AND Rybrevant (amivantamab) will be given as monotherapy. Non-small cell lung cancer (NSCLC) [Combination Therapy]: The member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND The NSCLC has documented epidermal growth factor receptor (EGFR) exon 20 insertion mutations (e.g. as detected by a FDA-approved test) AND Rybrevant (amivantamab) will be given in combination with carboplatin and pemetrexed in the first line setting. NSCLC EGFR Exon 19 Deletion or Exon 21 L858R Mutated [Lazcluze (lazertinib) Combination]: The member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND The NSCLC has documented epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations AND Rybrevant (amivantamab) will be given in combination with Lazcluze (lazertinib) in the first-line setting. NSCLC EGFR Exon 19 Deletion or Exon 21 L858R Mutated [Other Combination Therapy]: The member has a diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND The NSCLC has documented epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations AND Rybrevant (amivantamab) will be given in combination with Lazcluze (Iazertinib) in the first-line setting. NSCLC EGFR Exon 19 Deletion or Exon 21 L858R substitution mutations AND The member has experienced disease progression on or after an EGFR tyrosine kinase inhibitor [e.g. Tagrisso (osimeritinib)] AND Rybrevant (amivantamab) will be given in combination with carboplatin and pemetrexed as subsequent line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	

# RYBREVANT - VIAL (ML)

Part B Prerequisite
------------------------

#### **RYDAPT - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	AML newly diagnosied and AML relapsed/refractory: Members that have experienced disease progression while on or following Rydapt (midostaurin), Members that are using Rydapt(midostaurin) for post- consolidation therapy. Systemic Mastocytosis: Members that have experienced disease progression while on or following Rydapt (midostaurin).
Required Medical Information	Acute Myeloid Leukemia-Newly diagnosed: The member has newly diagnosed acute myeloid leukemia (AML) AND The member has documented FLT3 mutation-positive disease AND The member will be using Rydapt (midostaurin) in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy. Systemic Mastocytosis: The member has a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematologic neoplasm (SM-AHN), or mast cell leukemia (MCL). Acute Myeloid Leukemia - Relapsed/Refractory: The member has relapsed or refractory acute myeloid leukemia (AML) AND The member has documented FLT3 mutation-positive disease AND The member will be using Rydapt (midostaurin) as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

# RYLAZE - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with a history of serious pancreatitis with prior asparaginase based therapy. Members with a history of serious thrombosis with prior asparaginase based therapy. Members with a history of serious hemorrhagic events with prior asparaginase based therapy. Members that have experienced disease progression while on asparaginase based therapy.
Required Medical Information	Acute Lymphoblastic Leukemia (ALL) or Lymphoblastic Lymphoma (LBL): The member has a diagnosis of acute lymphoblastic leukemia (ALL) or Lymphoblastic lymphoma (LBL) AND The member has documented, Grade 2 - 4 hypersensitivity (based on Common Terminology Toxicity Criteria) as a result of prior treatment with Oncaspar (pegaspargase) ANDThe member is using Rylaze (asparaginase Erwinia chrysanthemi-rywn) as a component of a multi- agent chemotherapeutic regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

# RYTELO - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Myelodysplastic syndrome (MDS) related anemia: The member has a diagnosis of myelodysplastic syndromes (MDS) AND The member has a low- to intermediate-1 risk disease according to the International Prognostic Scoring System (IPSS) AND The member has transfusion-dependent anemia requiring 4 or more blood cell units over 8 weeks AND The member has not responded to or has lost response to or is ineligible for erythropoiesis-stimulating agents (ESA) (e.g., Retacrit, Procrit).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### sajazir - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hereditary Angioedema (HAE): The member must have a diagnosis of hereditary angioedema (HAE) type 1 or type 2. The member must have documentation of: Evidence of C4 level consistent with diagnosis of HAE Type 1 or 2 AND C1 inhibitor (C1INH) antigenic level consistent with diagnosis of HAE Type 1 or 2 OR C1INH functional level consistent with diagnosis of HAE Type 1 or 2 OR Known HAE-causing C1INH mutation AND The member has a history of recurrent angioedema in the absence of concomitant urticaria AND There are no concomitant or recent use of medications known to cause angioedema (e.g. ACEIs, ARBs) AND Other potential causes of angioedema have been ruled out or considered. The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). Must provide lab report or medical record documentation which include lab values as required by policy. Lab values must include C1q level that is consistent with the diagnosis of HAE. Note: according to the US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema, C1q level is useful to help distinguish between HAE-C1INH and acquired C1INH deficiency. C1q levels are decreased in 80% of acquired C1INH deficiency and rarely low in HAE-C1INH. The member is using icatibant for treatment of acute attacks of HAE.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### SANDOSTATIN LAR DEPOT - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Acromegaly: The member must have a diagnosis of Acromegaly. Must have had an inadequate response to surgery/radiation or for whom surgical resection/radiation is not an option. Treatment of metastatic carcinoid tumors. Must have a diagnosis of a carcinoid tumor. Patient must have severe diarrhea and flushing resulting from carcinoid tumor. Treatment of vasoactive intestinal peptide tumors (VIPomas). Patient must be diagnosed with a vasoactive intestinal peptide tumor. Patient must have diagnosis of profuse watery diarrhea associated with VIP- secreting tumor. Treatment of chemotherapy or radiation induced diarrhea. Patient must have grade 3 or above diarrhea according to NCI common toxicity. Patient must have NCI grade 1 or 2 diarrhea and have failed treatment with loperamide or diphenoxylate and atropine. Treatment of severe secretory diarrhea in acquired immune deficiency syndrome (AIDS) patients. Patient must have diagnosis of severe diarrhea resulting from acquired immune deficiency syndrome (AIDS). Patient must have tried and failed antimicrobial agents (eg. ciprofloxacin or metronidazole) and/or anti-motility agents (eg. loperamide or diphenoxylate and atropine). Reversal of life-threatening hypotension due to carcinoid crisis during induction of anesthesia. Patient must have life-threatening hypotension due to carcinoid crisis.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

### SANTYL - OINTMENT (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Wound Debridement: Member has a chronic dermal ulcer (e.g. pressure ulcer, venous ulcer, diabetic ulcer) or severely burned areas AND Member will be using Santyl (collagenase) for wound debridement.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### sapropterin - POWDER IN PACKET (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Phenylketonuria (PKU): The member has a diagnosis of PKU.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### SARCLISA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on or following an anti-CD38 inhibitor (e.g. daratumumab, isatuximab-irfc).
Required Medical Information	Multiple myeloma (third line). The member has a diagnosis of multiple myeloma AND The member will be using Sarclisa (isatuximab-irfc) in combination with Pomalyst (pomalidomide) and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The member has received at least two prior therapies including Revlimid (lenalidomide) and a proteasome inhibitor (e.g. bortezomib, carfilzomib). Multiple Myeloma (relapsed or refractory): The member has a diagnosis of relapsed or refractory multiple myeloma AND The member will be using Sarclisa (isatuximab- irfc) in combination with carfilzomib and dexamethasone (Omission of corticosteroid from regimen is allowed if intolerance/contraindication) AND The member has received at least one prior therapy. Newly Diagnosed Multiple Myeloma: The member has newly diagnosed multiple myeloma AND The member is ineligible for autologous stem cell transplant AND The member will be using Sarclisa (isatuximab- irfc) in combination with carfil be using Sarclisa (isatuximab- int) and the member has newly diagnosed multiple myeloma and the member has newly diagnosed multiple myeloma and the member is ineligible for autologous stem cell transplant AND The member will be using Sarclisa (isatuximab-irfc) in combination with bortezomib, lenalidomide, and dexamethasone.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

#### **SCEMBLIX - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Scemblix (asciminib).
Required Medical Information	Chronic Myeloid Leukemia (chronic phase): The member has a diagnosis of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase AND One of the following applies: The member has newly diagnosed disease OR The member has previously treated disease OR The member has T315I mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### SECUADO - PATCH, TRANSDERMAL 24 HOURS

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member has diagnosis of schizophrenia. The member must have prior therapy or intolerance or contraindication to at least two of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, lurasidone.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# SIGNIFOR - AMPUL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cushings disease: Diagnosis of Cushings disease AND Pituitary surgery is not an option or has not been curative AND No severe hepatic impairment (Child-Pugh C).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### sildenafil (pulm.hypertension) - TABLET

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension(PAH): The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### **SIRTURO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Multidrug-resistant tuberculosis (MDR-TB). The member must have a diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) confirmed by drug susceptibility testing (DST). Bedaquiline will be used as part of a multidrug regimen.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	24 weeks duration
Other Criteria	
Part B Prerequisite	0

#### **SKYRIZI - WEARABLE INJECTOR**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Plaque Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Moderately to severely active Crohns disease: member has a diagnosis of moderately to severely active Crohns disease. Moderately to severely active colitis: The member must have a diagnosis of moderately to severely active ulcerative colitis.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### sodium oxybate - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Narcolepsy with Cataplexy: The member has a diagnosis of narcolepsy with cataplexy. Narcolepsy with excessive daytime sleepiness: The member has a diagnosis of narcolepsy according to ICSD-3 or DSM-5 criteria AND the member has condition of excessive daytime sleepiness (EDS) associated with narcolepsy as confirmed by documented sleep testing (e.g. polysomnography, multiple sleep latency test) AND previous treatment, intolerance, or contraindication to at least one CNS stimulant (e.g. methylphenidate or amphetamine salt combination immediate release) or modafinil or armodafinil.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	The member will be using no more than one of the following products at any given time: Xyrem (sodium oxybate), Xywav (calcium magnesium, potassium, and sodium oxybates), Lumryz (sodium oxybate), Sunosi (solriamfetol), or Wakix (pitolisant).
Part B Prerequisite	0

# SOMAVERT - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acromegaly. The member must have a diagnosis of acromegaly AND The member had inadequate response to surgery or radiation therapy AND The member has had previous treatment, contraindication, or intolerance to one dopamine agonists (i.e. bromocriptine) or one somatostatin analogues (i.e. octreotide, Somatuline depot).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### sorafenib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Nexavar (sorafenib).
Required Medical Information	Renal Cell Carcinoma: Diagnosis of advanced renal cell carcinoma (stage IV) AND the member has experienced intolerance, contraindication, or unable to achieve treatment goals with Cabometyx (cabozantinib) as second line therapy (e.g., severe hypertension/hypertensive crisis, cardiac failure, venous thromboembolic event within the last 6 months, arterial thromboembolic event within the last 12 months, severe hemorrhage, reversible posterior leukoencephalopathy, unmanageable fistula/GI perforation, nephrotic syndrome). Liver Carcinoma: Diagnosis of unresectable hepatocellular (liver) carcinoma. Thyroid Carcinoma. Diagnosis of advanced metastatic medullary carcinoma (thyroid carcinoma) OR The member has a diagnosis of advanced, clinically progressive and/or symptomatic papillary carcinoma, follicular carcinoma or Hurthle cell carcinoma AND Tumors are not responsive to radio-iodine treatment. Gastrointestinal stromal tumor (GIST). Diagnosis of gastrointestinal stromal tumor (GIST) AND The member experienced disease progression with imatinib or Sutent (sunitinib) or Stivarga (regorafenib).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **SPRYCEL - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on dasatinib. For ALL and CML: The member has one of the following mutations: T315I/A, F317L/V/I/C or V299L.
Required Medical Information	Chronic Myelogenous Leukemia (CML): The member has a diagnosis of Ph+ chronic myeloid leukemia (CML) and one of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated and one of the following applies: Intermediate- or high-risk score for disease progression OR Low risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib OR The member has a diagnosis of chronic phase CML that has received previous treatment. Acute Lymphoblastic Leukemia (ALL): The member has ALL (Philadelphia Chromosome positive) and dasatinib is being used for induction or consolidation treatment in combination with chemotherapy or corticosteroids OR treatment is for maintenance therapy or the treatment of members with resistance or intolerance to prior therapy. Advanced Gastrointestinal Stromal Tumor (GIST): The member has a diagnosis of advanced unresectable GIST. The member has progressive disease or is intolerant to prior therapy with Gleevec (imatinib) or Sutent (sunitinib) or Stivarga. [Pediatric] Chronic Myelogenous Leukemia (CML). The member has a diagnosis of chromosome positive (Ph+) AND the member is in chronic phase. [Pediatric] Acute lymphoblastic leukemia (ALL). The member has a diagnosis of acute lymphoblastic leukemia (ALL). AND the member has Philadelphia chromosome positive (Ph+) disease AND the member has newly-diagnosed disease AND The member will be using dasatinib in combination with chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### STELARA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis (SC formulation only): The member must have a diagnosis of moderate to severe chronic plaque psoriasis AND The member has had prior therapy or intolerance to one or more oral systemic tretaments (e.g. methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic arthritis (SC formulation only): The member must have a diagnosis of active psoriatic arthritis. Moderately to severely active Crohn's disease (IV and SC formulations). The member must have a diagnosis of moderately to severely active colitis (IV and SC formulations): The member must have a diagnosis of active ulcerative colitis (IV and SC formulations): The member must have a diagnosis of moderately to severely active ulcerative colitis.
Age Restriction	Moderate to severe chronic plaque psoriasis and psoriatic arthritis: The member must be 6 years of age or older. For all other indications: Must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **STIVARGA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Stivarga (regorafenib).
Required Medical Information	Metastatic Colorectal Cancer. The member has a diagnosis of metastatic colorectal cancer AND The member is using Stivarga (regorafenib) as monotherapy AND The member has experienced disease progression, intolerance, or contraindication with ALL of the following therapies: fluoropyrimidine (regimens include 5-FU/capecitabine),oxaliplatin-based chemotherapy, irinotecan-based chemotherapy, and anti-VEGF therapy (e.g., bevacizumab, ziv-aflibercept) AND If the member is RAS wild-type*, has experienced disease progression, intolerance, or contraindication with anti-EGFR therapy (e.g., cetuximab, panitumumab).*This criteria only applies to left sided tumors. Gastrointestinal Stromal Tumor. The member has a diagnosis of locally advanced, unresectable or metastatic gastrointestinal stromal tumor AND The member has experienced disease progression, intolerance, or contraindication with imatinib mesylate and sunitinib malate. Hepatobiliary Cancers: The member has a diagnosis of hepatocellular carcinoma AND Stivarga (regorafenib) is being given as monotherapy AND The member has experienced progression after first line theapy (e.g., sorafenib). Soft Tissue sarcoma. Diagnosis of advanced or metastatic soft tisuse sarcoma (e.g., angiosarcoma, non-adipocytic sarcoma, pleomorphic rhabdomyosarcoma) AND Stivarga (regorafenib) is being given as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Month Duration
Other Criteria	
Part B Prerequisite	0

## STRENSIQ - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hypophosphatasia (HPP): The member must have a diagnosis of perinatal-onset, infantile-onset, or juvenile-onset hypophosphatasia based on the following criteria: one of the following: clinical signs and symptoms supporting onset of hypophatasia prior to 18 years of age OR radiographic evidence supporting hypophosphatasia diagnoses prior to 18 years of age AND one of the following: documented gene mutation of tissue-nonspecific alkaline phosphatase (TNSALP) OR Low total serum alkaline phosphatase (ALP) activity determined by the gender- and age- specific reference range, AND Elevated urine concentration of phosphoethanolamine (PEA) determined by age-specific reference range, OR Elevated serum pyridoxal 5'-phosphate (PLP) level (normal range 5 - 50 mcg/L), OR Documented gene mutation of tissue- nonspecific alkaline phosphatase (TNSALP).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### sunitinib malate - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on sunitinib. Member not to exceed a total treatment of 54 weeks (applicable to adjuvant therapy for renal cell carcinoma).
Required Medical Information	Gastrointestinal stromal tumor (GIST). Diagnosis of gastrointestinal stromal tumor (GIST)AND the member has disease progression on or intolerance to imatinib mesylate. Advanced renal cell carcinoma (RCC).Diagnosis of advanced renal cell carcinoma (stage IV). Renal Cell Carcinoma (RCC) Adjuvant Therapy. The member has high risk (i.e. tumor stage T3 or higher, regional lymph node metastases, or both) of recurrent RCC following nephrectomy AND sunitinib will be used as a single agent as adjuvant treatment. Pancreatic neuroendocrine tumors (PNET). Diagnosis of Progressive, well-differentiated pancreatic neuroendocrine tumors (pNET) AND The member has unresectable locally advanced or metastatic disease. Advanced Thyroid Carcinoma. Diagnosis of advanced/metastatic follicular carcinoma, Hurthle cell carcinoma) clinical trials are not available or appropriate AND The follicular, papillary, or Hurthle cell carcinoma is not responsive to radio-iodine treatment OR The member has a diagnosis of advanced medullary carcinoma-disseminated symptomatic disease (type of thyroid carcinoma) and has disease progression or has an intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). Advanced/Metastatic Angiosarcoma AND sunitinib is being utilized as a single agent/monotherapy (without concomitant chemotherapy or biologics). Thymomas/thymic carcinoma: The member has a diagnosis of thymic carcinoma/thymomas and the member will be using as monotherapy in the second line.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### SYMPAZAN - FILM, MEDICATED (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut Syndrome (LGS) AND Sympazan (clobazam film) will be used in combination with at least one other drug for controlling seizures AND the member has had prior therapy with AND has a documented contraindication (e.g., dysphagia) to BOTH generic clobazam tablet AND oral suspension formulation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# SYNRIBO - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Synribo (omacetaxine mepesuccinate).
Required Medical Information	Chronic Myelogenous Leukemia. The member has a diagnosis of chronic or accelerated phase chronic myeloid leukemia AND one of the following applies: The member has had prior therapy, intolerance, or resistance to at least two of the following tyrosine kinase inhibitors: imatinib, dasatinib, Tasigna, or Bosulif OR The member has a documented T315I mutation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **TABRECTA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Tabrecta (capmatinib).
Required Medical Information	Non-Small Lung Cell Cancer (NSCLC): The member has a diagnosis of metastatic NSCLC AND the disease is documented MET exon 14 skipping positive.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### tadalafil - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Benign Prostatic Hyperplasia (BPH). The member has a diagnosis of BPH. The member has failed previous treatment or has a contraindication/intolerance to an alpha blocker (i.e. terazosin, doxazosin, tamsulosin, alfuzosin, silodosin) AND 5-alpha reductase inhibitor (i.e. finasteride, dutasteride).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### tadalafil (pulm. hypertension) - TABLET

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Pulmonary Arterial Hypertension (PAH). The member must have a diagnosis of pulmonary arterial hypertension (WHO Group I) confirmed by right heart catheterization.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

#### **TAFINLAR - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Melanoma - Unresectable or metastatic, Anaplastic Thyroid Cancer, Metastatic Solid Tumors: Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab) Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Tafinlar (dabrafenib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinst (trametinib)]. Non-small cell lung cancer: Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab) Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib)]. Adjuvant melanoma: member is taking Tafinlar (dabrafenib) total treatment for more than one year. Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab) Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab) Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinst (trametinib)]. Low-grade Glioma: Members that have experienced disease progression while on Tafinlar (dabrafenib). Members that have experienced disease progression while on prior anti- BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib)].

#### **TAFINLAR - CAPSULE**

Required Medical Information	Melanoma - Unresectable or Metastatic: The member has a diagnosis of unresectable or stage IV metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND The member will be using Tafinlar (dabrafenib) as monotherapy OR in combination with Mekinist (trametinib). Non-small cell lung cancer: The member has a diagnosis of recurrent or metastatic non-small cell lung cancer (NSCLC) AND The member has a documented BRAF V600E mutation AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib). Melanoma - Adjuvant. The member has a diagnosis of stage III melanoma AND The member has undergone lymph node resection of involved lymph nodes AND The member will be using Tafinlar (dabrafenic) in combination with Mekinist (trametinib) for adjuvant treatment. Anaplastic Thyroid Cancer. The member has a diagnosis of locally advanced or metastatic anaplastic thyroid cancer AND The member has a documented V600E mutation AND The member has no satisfactory locoregional treatment options AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib). Metastatic Solid Tumors: the member has a diagnosis of unresectable or metastatic solid tumors with documented BRAF V600E mutation AND the member has disease that has progressed on prior therapy and has no satisfactory alternative treatments AND Tafinlar is given in combination with Mekinist. Low-grad Glioma: The member has a diagnosis of low-grade glioma
	(LGG) AND The member has a documented BRAF V600E mutation AND Tafinlar (dabrafenib) will be used in combination with Mekinist (trametinib).
Age Restriction	Low-grade Glioma only: The member is a pediatric age 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Low-grade Glioma: Plan year duration. All other indications: 6 months duration.
Other Criteria	
Part B Prerequisite	0

### **TAGRISSO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members who have disease progression on Tagrisso (osimertinib) (applicable to adjuvant therapy in NSCLC and NSCLC locally advanced, unresectable stage III). Total treatment exceeds three years (applicable to adjuvant therapy in NSCLC).
Required Medical Information	Non small cell lung cancer NSCLC: The member has a diagnosis of advanced or metastatic non small cell lung cancer (NSCLC) and ONE of the following criteria applies: The member has documented sensitizing EGFR mutations (exon 19 deletions or exon 21 L858R) AND Tagrisso (osimertinib) is being used as single agent for first line therapy OR Tagrisso (osimertinib) is being used in combination with pemetrexed and platinum-based chemotherapy (e.g., cisplatin, carboplatin) as first-line therapy OR The member has a diagnosis of advanced or metastatic non small cell lung cancer (NSCLC) and The member has a documented epidermal growth factor receptor (EGFR) T790M mutation AND Tagrisso (osimertinib) is used as monotherapy after progression of EGFR inhibitors (e.g., erlotinib, gefitinib). Non-small cell lung cancer (NSCLC) [Adjuvant therapy]: The member has a diagnosis of NSCLC (i.e., Stage IB- IIIA) AND The member has documented sensitizing EGFR mutations (exon 19 deletions or exon 21 L858R) AND The tumor has been resected AND Member will be taking (osimertinib) as a single agent for adjuvant therapy. Non-small cell lung cancer (NSCLC) - Locally Advanced, Unresectable [Stage III]: The member has a diagnosis of locally advanced, unresectable (stage III) NSCLC AND The disease has not progressed during or following concurrent or sequential platinum- based chemoradiation therapy AND The member has a documented sensitizing EGFR mutation (exon 19 deletion or exon 21 L858R) AND Tagrisso (osimertinib) will be given as a single agent as consolidation therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## TALVEY - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Talvey (talq uetamab).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member has relapsed/refractory disease AND The member has received at least four prior lines of therapy, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib), and an immunomodulatory agent (e.g. lenalidomide) AND The member is using Talvey (talquetamab) as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **TALZENNA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members have experienced disease progression while on or following PARP inhibitor therapy (eg, olaparib).
Required Medical Information	Breast Cancer. Member has a diagnosis of locally advanced or metastatic, HER-2 negative breast cancer AND Member has documented deleterious germline or suspected germline BRCA mutated disease AND if member has hormone receptor positive disease then is endocrine refractory AND Talzenna (talazoparib) will be used as monotherapy. Metastatic Castration-Resistant Prostate Cancer (mCRPC). Member has a diagnosis of Metastatic Castration-Resistant Prostate Cancer (mCRPC) AND Member has a documented (HRR) gene-mutated disease AND Member will use Talzenna (talazoparib) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or concurrent GnRH analog) AND Talzenna (talazoparib) is given in combination with Xtandi (enzalutamide).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **TASIGNA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Tasigna (nilotinib). For ALL and CML: The member has one of the following mutations: T315I, Y253H, E255K/V, or F359V/C/I.
Required Medical Information	Chronic Myelogenous Leukemia (CML). The member has a diagnosis of Philadelphia chromosome positive chronic myeloid leukemia (CML) AND One of the following applies: The member has accelerated or blast phase CML OR The member has a diagnosis of chronic phase CML that has not been previously treated, and one of the following applies: Intermediate- or high-risk score for disease progression OR Low-risk score for disease progression and has contraindication to, intolerance to, or unable to achieve treatment goals with imatinib OR The members has a diagnosis of chronic phase CML that has received previous treatment. Advanced Gastrointestinal Stromal Tumor (GIST). Diagnosis of advanced unresectable GIST.The member has progressive disease or is intolerant to prior therapy with Gleevec (imatinib), Sutent (sunitinib), or Stivarga. Acute Lymphoblastic Leukemia (ALL). The member has diagnosis of Philadelphia positive acute lymphoblastic leukemia. Pediatric CML: Diagnosis of chronic phase Ph+ chronic myeloid leukemia (CML) OR Diagnosis of accelerated phase Ph+ chronic myeloid leukemia (CML) AND resistance, intolerance, or contraindication to prior TKI therapy.
Age Restriction	Pediatric CML- member is greater than or equal to 1 year of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### tasimelteon - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Non-24-Hour Sleep-Wake Disorder. The member has a documented diagnosis of Non-24-Hour Sleep-Wake Disorder. Smith-Magenis Syndrome (SMS): The member has a documented diagnosis of SMS AND documented evidence of nighttime sleep disturbances associated with SMS.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### TAZVERIK - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member experiences disease progression on Tazverik
Required Medical Information	Epithelioid Sarcoma: The member has a diagnosis of metastatic or locally advanced epithelioid sarcoma not eligible for complete resection AND Tazverik will be given as monotherapy. Follicular lymphoma: The member has a diagnosis of relapsed/refractory follicular lymphoma AND one of the following applies: The member has a documented EZH2 mutation by an FDA approved test and the member has received at least two prior therapies and the member will be using Tazverik (tazemetostat) as monotherapy OR The member has no satisfactory alternative treatment options and The member will be using Tazverik (tazemetostat) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

## TECENTRIQ - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant setting for Non-Small Cell Lung Cancer: member is taking Tecentriq (atezolizumab) total treatment for more than one year.
Required Medical Information	Non-Small Cell Lung Cancer (advanced or metastatic): The member has a diagnosis of advanced or metastatic NSCLC AND member has disease with no EGFR or ALK genomic tumor aberrations and one of the following scenarios is applied: The member has non-squamous cell histology AND Tecentriq will be given as a component of one of the two combo regimens: in combination with carboplatin and paclitaxel and Bevacizumab Product as first line therapy followed by maintenance therapy with combination Tecentriq and Bevacizumab Product OR in combo with Abraxane (nabpaclitaxel) and carboplatin as first line therapy. OR Disease has high PD-L1 expression [PD-L1 stained greater than or equal to 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering greater than or equal to 10% of the tumor area] AND PD-L1 tumor expression is determined by an FDA-approved test AND will be given as first-line therapy AND The member will be using as monotherapy. OR The member has experienced disease progression on or after chemotherapy and EGFR inhibitor or ALK inhibitor (post confirmed EGFR or ALK genomic tumor aberration positivity) AND The member will be using Tecentriq as monotherapy. Alveolar Soft Part Sarcoma (ASPS): The member has a diagnosis of unresectable or metastatic alveolar soft part sarcoma AND The member will be using Tecentriq as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## TECENTRIQ - VIAL (ML)

Other Criteria	Small Cell Lung Cancer: The member has a diagnosis of extensive-stage small cell lung cancer AND Tecentriq will be given in combination with etoposide and carboplatin as first line therapy followed by maintenance therapy with Tecentriq. Heptatocellular Carcinoma: The member has a diagnosis of unresectable or metastatic hepatocellular carcinoma AND Tecentriq (atezolizumab) will be used as first line therapy in combination with bevacizumab. Melanoma: The member has a diagnosis of unresectable or metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND the member will use Tecentriq in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib). Non-Small Cell Lung Cancer (Adjuvant): The member must have a diagnosis of Stage II to IIIA non-small cell lung cancer AND The disease has expression of PD-L1 on greater than or equal to 1% of tumor cells as determined by an FDA-approved test AND The member is post complete surgical resection and adjuvant platinum-based chemotherapy AND The member will be using Tecentriq (atezolizumab) as monotherapy in the adjuvant setting.
Part B Prerequisite	0

## TECENTRIQ HYBREZA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Disease progression while on or following anti-PD-1/PD-L1 therapy (e.g. Opdivo [nivolumab], Keytruda [pembrolizumab], Tecentriq [atezolizumab], Bavencio [avelumab]). Adjuvant setting for Non-Small Cell Lung Cancer: member is taking Tecentriq (atezolizumab) total treatment for more than one year.
Required Medical Information	Non-Small Cell Lung Cancer (advanced or metastatic): The member has a diagnosis of advanced or metastatic NSCLC AND member has disease with no EGFR or ALK genomic tumor aberrations and one of the following scenarios is applied: The member has non-squamous cell histology AND Tecentriq will be given as a component of one of the two combo regimens: in combination with carboplatin and paclitaxel and Bevacizumab Product as first line therapy followed by maintenance therapy with combination Tecentriq and Bevacizumab Product OR in combo with Abraxane (nabpaclitaxel) and carboplatin as first line therapy. OR Disease has high PD-L1 expression [PD-L1 stained greater than or equal to 50% of tumor cells OR PD-L1 stained tumor-infiltrating immune cells covering greater than or equal to 10% of the tumor area] AND PD-L1 tumor expression is determined by an FDA-approved test AND will be given as first-line therapy AND The member will be using as monotherapy. OR The member has experienced disease progression on or after chemotherapy and EGFR inhibitor or ALK inhibitor (post confirmed EGFR or ALK genomic tumor aberration positivity) AND The member will be using Tecentriq as monotherapy. Alveolar Soft Part Sarcoma (ASPS): The member has a diagnosis of unresectable or metastatic alveolar soft part sarcoma AND The member will be using Tecentriq as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## TECENTRIQ HYBREZA - VIAL (ML)

Other Criteria	Small Cell Lung Cancer: The member has a diagnosis of extensive-stage small cell lung cancer AND Tecentriq will be given in combination with etoposide and carboplatin as first line therapy followed by maintenance therapy with Tecentriq. Heptatocellular Carcinoma: The member has a diagnosis of unresectable or metastatic hepatocellular carcinoma AND Tecentriq (atezolizumab) will be used as first line therapy in combination with bevacizumab. Melanoma: The member has a diagnosis of unresectable or metastatic melanoma AND The member has a documented BRAF V600 activating mutation AND the member will use Tecentriq in combination with Cotellic (cobimetinib) and Zelboraf (vemurafenib). Non-Small Cell Lung Cancer (Adjuvant): The member must have a diagnosis of Stage II to IIIA non-small cell lung cancer AND The disease has expression of PD-L1 on greater than or equal to 1% of tumor cells as determined by an FDA-approved test AND The member is post complete surgical resection and adjuvant platinum-based chemotherapy AND The member will be using Tecentriq (atezolizumab) as monotherapy in the adjuvant setting.
Part B Prerequisite	0

## TECVAYLI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on bispecific B- cell maturation antigen (BCMA)-directed CD3 T-cell engager-containing regimen.
Required Medical Information	Multiple Myeloma. The member has a diagnosis of multiple myeloma AND the member has relapsed/refractory disease AND the member has received at least four prior lines of therapy, including an anti-CD38 monoclonal antibody (e.g. daratumumab), a proteasome inhibitor (e.g. bortezomib), and an immunomodulatory agent (e.g. lenalidomide) AND the member is using Tecvayli (teclistamab-cqyv) as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## temsirolimus - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Patients that have experienced disease progression while on temsirolimus.
Required Medical Information	The member has a diagnosis of advanced/metastatic renal cell carcinoma (stage IV).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **TEPMETKO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member experiences disease progression on MET inhibitor (e.g., Tabrecta, Tepmetko).
Required Medical Information	Non-small cell lung cancer (NSCLC). The member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND The disease is documented MET exon 14 skipping positive.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### teriflunomide - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease, OR the member has a diagnosis of clinically isolated syndrome (CIS).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### testosterone - GEL IN METERED-DOSE PUMP

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member has one of the following diagnoses: Metastatic Breast Cancer (testosterone enanthate only) OR Delay Puberty in Males (testosterone enanthate only) OR Primary hypogonadism: testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals OR Hypogonadotropic hypogonadism: idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation AND Member has had one of the following: Documentation of two morning serum testosterone levels (total or free) that are less than the reference range for the lab, taken at separate times, prior to treatment OR Documentation of a serum testosterone level (total or free) that is less than or within the reference range for the lab, when already on treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### testosterone cypionate - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member has one of the following diagnoses: Metastatic Breast Cancer (testosterone enanthate only) OR Delay Puberty in Males (testosterone enanthate only) OR Primary hypogonadism: testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals OR Hypogonadotropic hypogonadism: idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation AND Member has had one of the following: Documentation of two morning serum testosterone levels (total or free) that are less than the reference range for the lab, taken at separate times, prior to treatment OR Documentation of a serum testosterone level (total or free) that is less than or within the reference range for the lab, when already on treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# testosterone enanthate - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Member has one of the following diagnoses: Metastatic Breast Cancer (testosterone enanthate only) OR Delay Puberty in Males (testosterone enanthate only) OR Primary hypogonadism: testicular failure due to cryptorchidism, bilateral torsion, orchitis, vanishing testis syndrome, orchiectomy, Klinefelter's syndrome, chemotherapy, or toxic damage from alcohol or heavy metals OR Hypogonadotropic hypogonadism: idiopathic gonadotropin or luteinizing hormone-releasing hormone (LHRH) deficiency or pituitary-hypothalamic injury from tumors, trauma, or radiation AND Member has had one of the following: Documentation of two morning serum testosterone levels (total or free) that are less than the reference range for the lab, taken at separate times, prior to treatment OR Documentation of a serum testosterone level (total or free) that is less than or within the reference range for the lab, when already on treatment.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### tetrabenazine - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Diagnosis of chorea associated with Huntington's disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# TEVIMBRA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Esophageal squamous cell carcinoma: The member has a diagnosis of unresectable or metastatic esophageal squamous cell carcinoma AND One of the following: Tevimbra (tislelizumab-jsgr) will be used as monotherapy AND the member has received prior systemic chemotherapy that did not include a PD-L1 inhibitor OR The member will be using Tevimbra (tislelizumab-jsgr) as first line therapy AND the tumor expresses PD-L1 (Combined Positive Score (CPS) greater than or equal to 1) AND tevimbra (tislelizumab-jsgr) will be used in combination with platinum-containing chemotherapy, followed by Tevimbra (tislelizumab- jsgr) monotherapy. Gastric or gastroesophageal junction adenocarcinoma: The member has a diagnosis of unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma AND The tumor is HER2-negative and PD-L1 positive (CPS greater than or equal to 1) AND Tevimbra (tislelizumab-jsgr) will be used as first line therapy AND Tevimbra (tislelizumab-jsgr) will be used as first line therapy AND Tevimbra (tislelizumab-jsgr) will be used in combination with platinum and fluoropyrimidine-based chemotherapy, followed by Tevimbra (tislelizumab-jsgr) monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **THALOMID - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on thalidomide.
Required Medical Information	Erythema Nodosum Leprosum (ENL). The member is currently having acute cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) OR Thalomid (thalidomide) is prescribed for maintenance therapy for prevention and suppression of the cutaneous manifestations of (ENL) recurrence. Multiple Myeloma. The member has a diagnosis of Multiple Myeloma. Waldenstrom's Macroglobulinemia. The member has a diagnosis of Waldenstrom's macroglobulinemia or lymphoplasmacytic lymphoma AND Thalomid (thalidomide) is being used for primary therapy, progressive or relapsed disease or salvage therapy for disease that does not respond to primary therapy AND Thalomid (thalidomide) is being used as monotherapy or in combination with a rituximab product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **TIBSOVO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on or following Tibsovo (ivosidenib)
Required Medical Information	Acute Myeloid Leukemia- Relapsed/Refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed or refractory disease AND The member has a documented IDH1 mutation AND one of the following applies: The member will be using Tibsovo (ivosedinib) as monotherapy OR the member will be using Tibsovo as a component of repeating the initial successful induction regimen, if late relapse (relapse occurring later than 12 months). Acute Myeloid Leukemia Newly diagnosed: The member has a diagnosis of acute myeloid leukemia (AML) AND the member has newly diagnosed disease AND one of the following applies: the member is not a candidate for intensive induction therapy due to comorbidities OR the member declines intensive induction therapy. The member has a documented IDH1 mutation AND the member will be using Tibsovo as monotherapy or in combination with azactidine. Cholangiocarcinoma: The member has locally advanced or metastatic cholangiocarcinoma AND the disease has documented isocitrate dehydrogenate-1 (IDH1) mutation AND Tibsovo (ivosedinib) will be a subsequent therapy and used as monotherapy. Myelodysplastic syndromes (MDS): The member has relapsed or refractory disease AND The member has a documented IDH1 mutation AND The member has a monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	MDS: Plan year duration. All other indications: 6 Months Duration
Other Criteria	
Part B Prerequisite	0

# TIVDAK - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Tivdak (tisotumab vedotin- tftv).
Required Medical Information	Recurrent/ Metastatic Cervical Cancer: The member has recurrent or metastatic cervical cancer AND The member experienced disease progression after chemotherapy AND If the disease expresses CPS score of greater than equal to 1 AND The member has a medical reason why Keytruda (pembrolizumab) cannot be initiated as subsequent therapy AND Tivdak (tisotumab vedotin-tftv) is administered as monotherapy as subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### topiramate - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Migraine Prophylaxis: Member is using for prophylaxis of migraine headache AND has had previous treatment with or intolerance to immediate release topiramate tablet or capsule AND has had previous treatment, intolerance, or contraindication with propranolol or timolol. Epilepsy Adjunctive Therapy: Member has a diagnosis of partial-onset (focal) seizures, primary generalized tonic-clonic seizures, or seizures associated with Lennox-Gastaut syndrome (LGS) AND Member will use Eprontia (topiramate) in combination with at least one other drug for controlling seizures AND Member has tried or cannot use immediate- release topiramate tablet or capsule. Epilepsy Monotherapy: Member has a diagnosis of partial-onset (focal) seizures or primary generalized tonic-clonic seizures AND Member has tried or cannot use immediate release topiramate tablet or capsule. Epilepsy Monotherapy: Member has a diagnosis of partial-onset (focal) seizures or primary generalized tonic-clonic seizures AND Member has tried or cannot use immediate
Age Restriction	Migraine Prophylaxis: Member must be 12 years of age or older. Epilepsy indications: Member must be 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### torpenz - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression while on everolimus.
Required Medical Information	Subependymal Giant Cell Astrocytoma (SEGA) with TSC [Adult and Pediatrics]: Member must have an intolerance or contraindication to generic everolimus AND The member has a diagnosis of SEGA associated with tuberous sclerosis complex (TSC) AND The member requires therapeutic intervention but is not a candidate for curative surgical resection. Angiomyolipoma and Tuberous Sclerosis Complex (TSC): Member must have an intolerance or contraindication to generic everolimus AND The member has a diagnosis of renal angiomyolipoma and tuberous sclerosis complex (TSC) AND Immediate surgery is not required. Metastatic Breast Cancer: Member must have an intolerance or contraindication to generic everolimus AND The member has a diagnosis of hormone receptor (HR) positive and human epidermal growth factor receptor 2 (HER2) negative metastatic disease AND The member has been treated with endocrine therapy (e.g., letrozole, anastrozole) AND The member will use everolimus in combination with exemestane or fulvestrant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# TRAZIMERA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	For Herceptin (trastuzumab), Ogivri, Herzuma or Ontruzant requests: member must have an intolerance or contraindication Trazimera (trastuzumab-qyyp) OR Kanjinti (trastuzumab-anns) and meets below criteria: Breast Cancer: The member has a diagnosis of breast cancer and HER2 (human epidermal growth factor receptor2) positive disease (e.g., defined as IHC 3+ or IHC2+/ISH positive). Gastric Cancer: The member has a diagnosis of advanced, gastric cancer or gastroesophageal adenocarcinoma and HER2 positive disease (e.g., defined as IHC 3+ or IHC2+/ISH positive) AND trastuzumab is being used in combination with cisplatin and fluorouracil or capecitabine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## TRELSTAR - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other LHRH agonists.
Required Medical Information	Prostate Cancer. The member has a diagnosis of advanced prostate cancer or has a high risk of disease recurrence.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### TREMFYA - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Plaque Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member has a diagnosis of moderately to severely active Crohn's Disease.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## TREMFYA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member has a diagnosis of moderately to severely active Crohn's Disease.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## TREMFYA PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Plaque Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member has a diagnosis of moderately to severely active Crohn's Disease.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## TREMFYA PEN INDUCTION PK-CROHN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Plaque Psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND the member has had prior therapy with or intolerance to a single conventional oral systemic treatment (e.g. methotrexate, cyclosporine), or contraindication to all conventional oral systemic treatments. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis. Ulcerative Colitis: The member has a diagnosis of moderate to severely active ulcerative colitis. Crohn's Disease: The member has a diagnosis of moderately to severely active Crohn's Disease.
Age Restriction	The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### tretinoin - CREAM (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Approval will be given to all members using this agent for medically necessary, FDA approved, or compendia supported, non-cosmetic indications including but not limited to the following: Acne: the member has a diagnosis of acne vulgaris, Actinic Keratosis: the member has a diagnosis of actinic keratosis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

### TRIKAFTA - TABLET, SEQUENTIAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cystic Fibrosis: The member must meet ALL of the following criteria: Diagnosis of Cystic Fibrosis AND Prior lab testing with documentation of a mutation in the CFTR gene that is responsive to therapy based on clinical literature and/or in vitro assay data.
Age Restriction	
Prescriber Restriction	The member is being treated by or in consultation with a specialist (e.g. pulmonologist).
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# TRISENOX - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute Promyelocytic Leukemia (APL). The member has a diagnosis of acute promyelocytic leukemia AND the member will be using Trisenox (arsenic trioxide) for induction therapy, consolidation therapy, or relapsed disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## TRODELVY - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members experienced disease progression on Trodelvy (sacituzumab govitecan-hziy)
Required Medical Information	Breast Cancer: The member has unresectable locally advanced or metastatic triple negative breast cancer AND The member has received at least two prior therapies, where one was administered for metastatic disease AND Trodelvy (sacituzumab govitecan-hziy) is given as single agent as subsequent therapy. Urothelial cancer: The member has locally advanced or metastatic urothelial cancer AND The member has received prior platinum containing chemotherapy AND The member has received prior PD-1 or PD-L1 inhibitor AND Trodelvy (sacituzumab govitecan-hziy) is given as single agent as subsequent therapy. Breast cancer (Hormone Receptor (HR)- positive): The member has a diagnosis of unresectable locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (e.g., IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer AND The member has received at least two additional systemic therapies in the metastatic setting (e.g. taxane) AND Trodelvy will be used as a single agent for subsequent therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# TRULICITY - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member is using for weight loss.
Required Medical Information	Diabetes Mellitus. The member has a diagnosis of type 2 diabetes mellitus.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### TRUQAP - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has progression while on Truqap (capivasertib).
Required Medical Information	HR-positive/HER2-negative metastatic breast cancer. Member has metastatic or locally advanced breast cancer AND Member has a diagnosis of hormone receptor (HR)-positive and human epidermal growth factor receptor 2 (HER2)-negative disease AND Member has one or more documented PIK3CA/AKTI/PTEN-alterations as detected by an FDA-approved test AND Member has progressed on at least one prior endocrine-based regimens [including one line containing a cyclin- dependent kinase (CDK) 4 and 6 inhibitor (e.g., ribociclib, abemaciclib, palbociclib)] and meets one of the following: Has been treated previously in the metastatic setting OR Has recurrence on or within 12 months of completing adjuvant therapy AND Member will be using Truqap (capivasertib) in combination with fulvestrant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### TUKYSA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Tukysa (tucatinib)
Required Medical Information	Breast Cancer. The member has metastatic or advanced unresectable HER 2 positive breast cancer (inclusive of brain metastases) and all of the following apply: Member has received one or more prior anti-HER2 based regimen in the metastatic setting AND Tukysa is given in combination with trastuzumab product and capecitabine as subsequent therapy. Colorectal cancer. The member has a diagnosis of RAS wild- type HER2-positive unresectable or metastatic colorectal cancer AND The member has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy AND Tuksya will be given in combination with trastuzumab product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **TURALIO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Symptomatic Tenosynovial Giant Cell Tumor: The member has symptomatic tenosynovial giant cell tumor (TGCT) and the disease is associated with severe morbidity or functional limitations and the disease is not amenable to improvement with surgery and Turalio (pexidartinib) will be used as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA
Part B Prerequisite	0

## TYMLOS - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of osteoporosis. The member is at high risk for osteoporotic fracture as evident by the following: The member has a history of osteoporotic fracture OR The member has new fractures or significant loss of bone mineral density despite previous treatment, contraindication or intolerance with an oral OR intravenous bisphosphonate (e.g. alendronate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **UBRELVY - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute Migraine: The member will be utilizing Ubrelvy (ubrogepant) for the acute treatment of migraines AND The member has had previous treatment, intolerance, or contraindication to ONE of the following: naratriptan, rizatriptan, sumatriptan.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## UDENYCA - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Febrile Neutropenia Prophylaxis: Concomitant use with filgrastim product or pegfilgrastim product (e.g., filgrastim, filgrastim-sndz, filgrastim-aafi, pegfilgrastim-jmbd, pegfilgrastim-cbqv) within seven days of pegfilgrastim dose. Same day administration with myelosuppressive chemotherapy or therapeutic radiation (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy) (NOTE: If the request is for Udenyca OnBody or Neulasta Onpro the product may be applied on the same day as myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis: The member must have a diagnosis of non-myeloid malignancy (e.g., solid tumors) AND The member has received or will receive pegfilgrastim product 24-72 hours after the administration of myelosuppressive chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and at least ONE of the following risk factor applies OR A risk of febrile neutropenia of less than 10% based on chemotherapy regimen, and at least TWO of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## UDENYCA - SYRINGE (ML)

Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.
Part B Prerequisite	0

## UDENYCA AUTOINJECTOR - AUTO-INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Febrile Neutropenia Prophylaxis: Concomitant use with filgrastim product or pegfilgrastim product (e.g., filgrastim, filgrastim-sndz, filgrastim-aafi, pegfilgrastim-jmbd, pegfilgrastim-cbqv) within seven days of pegfilgrastim dose. Same day administration with myelosuppressive chemotherapy or therapeutic radiation (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy) (NOTE: If the request is for Udenyca OnBody or Neulasta Onpro the product may be applied on the same day as myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis: The member must have a diagnosis of non-myeloid malignancy (e.g., solid tumors) AND The member has received or will receive pegfilgrastim product 24-72 hours after the administration of myelosuppressive chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and at least ONE of the following risk factor applies OR A risk of febrile neutropenia of less than 10% based on chemotherapy regimen, and at least TWO of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

## UDENYCA AUTOINJECTOR - AUTO-INJECTOR (ML)

Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.
Part B Prerequisite	0

#### UDENYCA ONBODY - SYRINGE, WITH WEARABLE INJECTOR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Febrile Neutropenia Prophylaxis: Concomitant use with filgrastim product or pegfilgrastim product (e.g., filgrastim, filgrastim-sndz, filgrastim-aafi, pegfilgrastim-jmbd, pegfilgrastim-cbqv) within seven days of pegfilgrastim dose. Same day administration with myelosuppressive chemotherapy or therapeutic radiation (Administration of pegfilgrastim occurs no less than 24 hours following myelosuppressive chemotherapy) (NOTE: If the request is for Udenyca OnBody or Neulasta Onpro the product may be applied on the same day as myelosuppressive chemotherapy). Cannot be given more than once per chemotherapy cycle.
Required Medical Information	Febrile Neutropenia Prophylaxis: The member must have a diagnosis of non-myeloid malignancy (e.g., solid tumors) AND The member has received or will receive pegfilgrastim product 24-72 hours after the administration of myelosuppressive chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and at least ONE of the following risk factor applies OR A risk of febrile neutropenia of less than 10% based on chemotherapy regimen, and at least TWO of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophil count less than 500 neutrophils/mcL or less than 1,000 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration

### UDENYCA ONBODY - SYRINGE, WITH WEARABLE INJECTOR

Other Criteria	Hematopoietic Subsyndrome of Acute Radiation Syndrome. The member has been acutely exposed to myelosuppressive doses of nontherapeutic radiation.
Part B Prerequisite	0

## UNITUXIN - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members receiving Unituxin (dinutuximab) as monotherapy. Members that have experienced disease progression while on Unituxin (dinutuximab).
Required Medical Information	High-risk neuroblastoma: The member has a diagnosis of high-risk neuroblastoma ANDUnituxin (dinutuximab) will be used in combination with isotretinoin AND Unituxin (dinutuximab) will be used in alternating cycles of Leukine (sargramostim) and Proleukin (aldesleukin) AND The member has achieved at least a partial response to the following: Induction combination chemotherapy AND Maximum feasible surgical resection The member has had the previous procedure/therapy: Myeloablative consolidation chemotherapy followed by autologous stem cell transplantation AND Radiation therapy to residual soft tissue disease.
Age Restriction	Memebr must be 18 years of age or younger.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## VALCHLOR - GEL (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Members that have experienced disease progression while on Valchlor (mechlorethamine).
Required Medical Information	Cutaneous T-Cell Lymphoma: The member has a diagnosis of fungoides-type cutaneous T-cell lymphoma AND The member has had prior therapy with skin-directed therapy or using as primary treatment.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	0

# valrubicin - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has an active urinary tract infection (UTI). The member has perforated bladder or compromised bladder mucosa. The member has small bladder capacity (unable to tolerate a 75 mL instillation).
Required Medical Information	Bladder Cancer: The member has recurrent or persistent carcinoma in situ of the urinary bladder(Cis). The member has experienced disease progression, intolerance or has a contraindication to BCG therapy. The member is not a candidate for immediate cystectomy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## VALSTAR - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has an active urinary tract infection (UTI). The member has perforated bladder or compromised bladder mucosa. The member has small bladder capacity (unable to tolerate a 75 mL instillation).
Required Medical Information	Bladder Cancer: The member has recurrent or persistent carcinoma in situ of the urinary bladder(Cis). The member has experienced disease progression, intolerance or has a contraindication to BCG therapy. The member is not a candidate for immediate cystectomy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

### VANFLYTA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following Vanflyta (quizartinib).
Required Medical Information	Acute Myeloid Leukemia (newly diagnosed). The member has newly diagnosed acute myeloid leukemia (AML) AND The member has documented FLT3 internal tandem duplication (ITD)-positive disease AND The member will be using Vanflyta (quizartinib) in combination with standard cytarabine and anthracycline induction and cytarabine consolidation chemotherapy OR The member will be using Vanflyta (quizartinib) as maintenance monotherapy following consolidation with systemic chemotherapy (excludes maintenance monotherapy following allogeneic hemopoietic stem cell transplantation).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

## VECTIBIX - VIAL (ML)

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria	Members with colorectal cancer (CRC) in which RAS mutation status is unknown. Member has had disease progression on Vectibix (panitumumab) or Erbitux (cetuximab).	
Required Medical Information	Metastatic Colorectal Cancer (mCRC). The member has a diagnosis of advanced or metastatic Colorectal Cancer (mCRC) AND the member has mCRC that is documented as wild-type, non-mutated KRAS and NRAS (wild-type RAS) AND ONE of the criteria following applies. Used as monotherapy in members who had disease progression on or following fluoropyrimidine (e.g., capecitabine, fluorouracil), oxaliplatin, and irinotecan containing chemotherapy regimens. OR Vectibix (panitumumab) will be used in combination with CAPEOX, FOLFOX or FOLFIRI OR Vectibix (panitumumab) will be used concurrently with irinotecan-based therapy in mCRC members. Colorectal Cancer [KRAS G12C-mutated]: The member has a diagnosis of metastatic colorectal cancer (mCRC) AND The disease is documented as KRAS G12C- mutated, as determined by an FDA-approved test AND The member has received prior systemic treatment with chemotherapy [fluoropyrimidine- based chemotherapy (e.g., 5-fluorouracil, capecitabine), oxaliplatin, irinotecan] AND Vectibix (panitumumab) will be given in combination with Lumakras (sotorasib).	
Age Restriction		
Prescriber Restriction	Licensed Practitioner	
Coverage Duration	Plan year duration	
Other Criteria		
Part B Prerequisite	0	

### **VENCLEXTA - TABLET**

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria	Members that have experienced disease progression while on Venclexta (venetoclax).	
Required Medical Information	Chronic Lymphocytic Leukemia (CLL):The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL) and one of the following applies: has received at least one prior therapy AND the member is using Venclexta (venetoclax) as monotherapy or in combination with rituximab OR the request is for first-line therapy AND the member is using Venclexta (venetoclax) in combination with Gazyva (obinutuzumab). Mantle Cell Lymphoma: The member has a diagnosis of MCL AND The member is using Venclexta (venetoclax) as monotherapy or in combination with a rituximab product AND The member meets one of the following: relapsed, refractory, or progressive disease OR Stable disease or partial response after induction therapy. Acute Myeloid Leukemia - Newly Diagnosed: The member has a diagnosis of newly- diagnosed acute myeloid leukemia (AML) AND one of the following applies: member is 75 years or older OR member has comorbidities that preclude the use of intensive induction chemotherapy (e.g. baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2- 3, severe cardiac or pulmonary comorbidity, moderate hepatic impairment, or creatinine clearance less than 45 ml/min). The member will be using Venclexcta (ventoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine. Acute Myeloid Leukemia, relapsed/refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed/refractory disease AND One of the following applies: As a component of repeating the initial successful induction regimen if late relapse (greater than or equal to 12 months since induction regimen) AND Venclexta (venetoclax) has not been administered continuously AND Venclexta (venetoclax) has not been administered continuously AND Venclexta (venetoclax) has not been administered continuously AND Venclexta (venetoclax) has not stopped due to the development of clinical resistance OR The member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine.	
Prescriber	Licensed Practitioner	
Restriction		
Coverage Duration	Plan year duration	
Other Criteria		

### **VENCLEXTA - TABLET**

Part B Prerequisite
------------------------

### VENCLEXTA STARTING PACK - TABLET, DOSE PACK

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria	Members that have experienced disease progression while on Venclex (venetoclax).	
Required Medical Information	Chronic Lymphocytic Leukemia (CLL):The member has a diagnosis of Chronic Lymphocytic Leukemia (CLL) and one of the following applies: has received at least one prior therapy AND the member is using Venclexta (venetoclax) as monotherapy or in combination with rituximab OR the request is for first-line therapy AND the member is using Venclexta (venetoclax) in combination with Gazyva (obinutuzumab). Mantle Cell Lymphoma: The member has a diagnosis of MCL AND The member is using Venclexta (venetoclax) as monotherapy or in combination with a rituximab product AND The member meets one of the following: relapsed, refractory, or progressive disease OR Stable disease or partial response after induction therapy. Acute Myeloid Leukemia - Newly Diagnosed: The member has a diagnosis of newly- diagnosed acute myeloid leukemia (AML) AND one of the following applies: member is 75 years or older OR member has comorbidities that preclude the use of intensive induction chemotherapy (e.g. baseline Eastern Cooperative Oncology Group (ECOG) performance status of 2- 3, severe cardiac or pulmonary comorbidity, moderate hepatic impairment, or creatinine clearance less than 45 ml/min). The member will be using Venclexcta (ventoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine. Acute Myeloid Leukemia, relapsed/refractory: The member has a diagnosis of acute myeloid leukemia (AML) AND The member has relapsed/refractory disease AND One of the following applies: As a component of repeating the initial successful induction regimen if late relapse (greater than or equal to 12 months since induction regimen) AND Venclexta (venetoclax) was not stopped due to the development of clinical resistance OR The member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine.	
Prescriber Restriction	Licensed Practitioner	
Coverage Duration	Plan year duration	
Other Criteria		

### VENCLEXTA STARTING PACK - TABLET, DOSE PACK

Part B	0		
Prerequisite			

#### **VERQUVO - TABLET**

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria		
Required Medical Information	Heart Failure: The member must meet ALL of the following criteria: Diagnosis of symptomatic chronic heart failure (e.g. NYHA Class II-IV) AND Left ventricular ejection fraction less than or equal to 45% AND Worsening cardiac event resulting in hospitalization or use of IV diuretics within the past six months.	
Age Restriction		
Prescriber Restriction	Licensed Practitioner	
Coverage Duration	Plan Year Duration	
Other Criteria		
Part B Prerequisite	0	

### VERSACLOZ - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must be using clozapine orally disintegrating tablet for treatment-resistant schizophrenia. The member must have had prior therapy or intolerance to generic clozapine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **VERZENIO - TABLET**

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria	Member has experienced disease progression on CDK 4/6 inhibitor (e.g., palbociclib, ribociclib). Member exceeds two years of total Verzenio (abemaciclib) based treatment (applicable only to early breast cancer).	
Required Medical Information	Metastatic Breast cancer- initial endocrine based therapy. The member has a diagnosis of advanced or metastatic hormone receptor (HR)- positive and human epidermal growth factor receptor 2 (Her2neu)- negative breast cancer AND Verzenio (abemaciclib) is given in combination with an aromatase inhibitor (e.g., letrozole) as first line endocrine based therapy. Metastatic breast cancer combination therapy with Faslodex (fulvestrant). The member has diagnosis of advanced or metastatic hormone receptor (HR) positive human epidermal growth factor receptor 2 (HER2) negative breast cancer AND The member has experienced disease progression on endocrine therapy (e.g., anastrazole) AND Verzenio (abemaciclib) is given in combination with Faslodex (fulvestrant). Metastatic breast cancer monotherapy: The member has diagnosis of advanced or metastatic HR positive, HER2 negative breast cancer AND the member has experienced disease progression on endocrine therapy (e.g., anastrazole) and chemotherapy in the metastatic setting AND Verzenio (abemaciclib) is being used as monotherapy. Early Breast cancer - combination therapy: The member has a diagnosis of HR positive, HER2 negative, node positive, early breast cancer at high risk of recurrence AND Verzenio (abemaciclib) is given in combination with tamoxifen or aromatase inhibitor.	
Age Restriction		
Prescriber Restriction	Licensed Practitioner	
Coverage Duration	6 months duration	
Other Criteria		
Part B Prerequisite	0	

## vigabatrin - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Refractory Complex Partial Seizure: Member has a diagnosis of refractory complex partial seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling complex partial seizures (e.g. levetiracetam, topiramate, carbamazepine, gabapentin, divalproex, or lamotrigine) AND vigabatrin will be used in combination with at least one other drug for controlling complex partial seizures. Infantile Spasms: Documented diagnosis of infantile spasms.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## vigadrone - POWDER IN PACKET (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Refractory Complex Partial Seizure: Member has a diagnosis of refractory complex partial seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling complex partial seizures (e.g. levetiracetam, topiramate, carbamazepine, gabapentin, divalproex, or lamotrigine) AND vigabatrin will be used in combination with at least one other drug for controlling complex partial seizures. Infantile Spasms: Documented diagnosis of infantile spasms.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## VIGAFYDE - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Infantile Spasms: The member has a documented diagnosis of infantile spasms.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## vigpoder - POWDER IN PACKET (EA)

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria		
Required Medical Information	Refractory Complex Partial Seizure: Member has a diagnosis of refractory complex partial seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling complex partial seizures (e.g. levetiracetam, topiramate, carbamazepine, gabapentin, divalproex, or lamotrigine) AND vigabatrin will be used in combination with at least one other drug for controlling complex partial seizures. Infantile Spasms: Documented diagnosis of infantile spasms.	
Age Restriction		
Prescriber Restriction	Licensed Practitioner	
Coverage Duration	Plan Year Duration	
Other Criteria		
Part B Prerequisite	0	

#### vilazodone - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Major depressive disorder: The member has a clinical diagnosis of major depressive disorder (MDD) as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND The member must have a documentation of prior therapy, intolerance, or contraindication to a selective serotonin reuptake inhibitor (SSRI) AND a generic bupropion product (75mg/100mg IR, 100mg/150mg/200mg SR, or 150mg/300mg XL) or mirtazapine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### **VITRAKVI - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Solid Tumors. Member has been diagnosed with advanced or metastatic solid tumor OR Member is not a candidate for surgical resection AND Member has a documented neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known resistance mutation AND Member is not a candidate for or does not have alternative systemic therapy treatment options.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **VIZIMPRO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Non-small cell lung cancer (NSCLC). The member has a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND the following criteria applies: The member has a documented epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 (L858R) substitution mutation AND The member is using Vizimpro (dacomitinib) as a single agent for first line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	0

#### **VONJO - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Vonjo (pacritinib).
Required Medical Information	Myelofibrosis: The member has a diagnosis of primary myelofibrosis or secondary myelofibrosis (i.e. post-polycythemia vera or post-essential thrombocythemia) AND The member has one of the following risk categories, as defined by accepted risk stratification tools for myelofibrosis (e.g. International Prognostic Scoring System (IPSS), Dynamic International Prognostic Scoring System (DIPSS), or DIPSS-PLUS): Intermediate-risk disease OR High-risk disease AND The member will be using Vonjo (pacritinib) as monotherapy AND The member has a platelet count below 50 x 109/L. Reauthorization criteria: Physician attestation that the member has continued to receive a clinical benefit (e.g. spleen volume reduction from baseline, symptom improvement) AND Physician attestation that the member has not experienced unacceptable toxicities.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial Authorization: 6 months duration. Reauthorization: 6 months duration
Other Criteria	
Part B Prerequisite	0

#### **VORANIGO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members have experienced disease progression while on Voranigo (vorasidenib).
Required Medical Information	Gliomas: The member has a diagnosis of grade 2 astrocytoma or oligodendroglioma AND The member has a documented isocitrate dehydrogenate-1 (IDH1) or isocitrate dehydrogenate-2 (IDH2) mutation AND The member is using Voranigo (vorasidenib) as single agent following surgery (i.e., biopsy, sub-total resection, or gross total resection).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### voriconazole - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Antifungal Prophylaxis in members undergoing bone marrow transplants. Antifungal Prophylaxis in members who are intermediate or high risk of developing cancer-related fungal infections. Prophylaxis of Aspergillus species in post-heart transplantation. Prophylaxis of both Candida and Aspergillus species in post-liver transplant. Prophylaxis of invasive aspergillosis in post-lung transplantation. Treatment of invasive aspergillosis, Treatment of chronic cavitary or necrotizing pulmonary aspergillosis and/or Serious fungal infections cause by Scedosporium apiospermum and Fusarium spp. including Fusarium solani, in patients intolerant of other therapy OR Empiric therapy of suspected invasive Candidiasis or Aspergillosis in high risk patients with febrile neutropenia despite receiving broad-spectrum antibiotic therapy. Diagnosis of one of the following fungal infections and failed to achieve clinical response or has contraindications to fluconazole or itraconazole for sensitive (non- krusei, non-glabrata) candida infections: Esophageal candidiasis, Oropharyngeal candidiasis,Candidemia in nonneutropenic patients and/or The following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and/or wounds.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration unless Liver/bone marrow TX: 1 month, Lung TX: 4 month, or Heart TX: 5 month.
Other Criteria	
Part B Prerequisite	0

## voriconazole-hpbcd - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Antifungal Prophylaxis in members undergoing bone marrow transplants. Antifungal Prophylaxis in members who are intermediate or high risk of developing cancer-related fungal infections. Prophylaxis of Aspergillus species in post-heart transplantation. Prophylaxis of both Candida and Aspergillus species in post-liver transplant. Prophylaxis of invasive aspergillosis in post-lung transplantation. Treatment of invasive aspergillosis, Treatment of chronic cavitary or necrotizing pulmonary aspergillosis and/or Serious fungal infections cause by Scedosporium apiospermum and Fusarium spp. including Fusarium solani, in patients intolerant of other therapy OR Empiric therapy of suspected invasive Candidiasis or Aspergillosis in high risk patients with febrile neutropenia despite receiving broad-spectrum antibiotic therapy. Diagnosis of one of the following fungal infections and failed to achieve clinical response or has contraindications to fluconazole or itraconazole for sensitive (non- krusei, non-glabrata) candida infections: Esophageal candidiasis, Oropharyngeal candidiasis,Candidemia in nonneutropenic patients and/or The following Candida infections: disseminated infections in skin and infections in abdomen, kidney, bladder wall, and/or wounds.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration unless Liver/bone marrow TX: 1 month, Lung TX: 4 month, or Heart TX: 5 month.
Other Criteria	
Part B Prerequisite	0

#### **VOSEVI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Retreatment of Chronic Hepatitis C. The member must have a diagnosis of chronic hepatitis C (HCV). The member must have HCV genotype documented prior to therapy. Baseline HCV RNA must be documented. The member has relapsed after completing a full course of or has a contraindication to Epclusa.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 weeks depending on disease state and genotype based on AASLD treatment guidelines for HCV.
Other Criteria	
Part B Prerequisite	0

#### **VOWST - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Prevention of recurrent Clostridioides difficile infection (CDI): Member has experienced at least one episode of Clostridioides difficile infection (CDI) and Vowst will be used to prevent recurrence of CDI AND Member has completed OR will complete CDI standard of care treatment (defined as 10-21 days of treatment with vancomycin 125 mg PO QID and/or fidaxomicin 200 mg PO BID) within 2-4 days before initiating Vowst AND Member must have performed bowel cleanse using magnesium citrate or polyethylene glycol electrolyte solution on the day prior to first dose of Vowst.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## VRAYLAR - CAPSULE, DOSE PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Schizophrenia: The member must be utilizing Vraylar for the treatment of schizophrenia AND The member must have documentation of prior therapy, intolerance, or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, or lurasidone. Bipolar I Disorder (manic or mixed episode): The member must be utilizing Vraylar for the treatment of bipolar I disorder (manic or mixed episode) AND The member must have documentation of prior therapy, intolerance, or contraindication to at least 2 of the following: risperidone, olanzapine, quetiapine, ziprasidone, or aripiprazole. Bipolar 1 Disorder (Bipolar Depression): The member must have a diagnosis of bipolar 1 disorder (bipolar depression) and the member must have documentation to quetiapine or lurasidone. Major Depressive Disorder: The member has a clinical diagnosis of major depressive disorder (MDD) as defined by DSM-5 criteria and/or appropriate depression rating scale (e.g. PHQ-9, Clinically Useful Depression Outcome Scale, Quick Inventory of Depressive Symptomatology-Self Report 16 Item, MADRS, HAM-D) AND The member has had previous treatment, contraindication, or intolerance to at least one antidepressant of adequate dose (i.e. as determined by the treating provider based on individual patient characteristics) and duration (i.e. at least 8 weeks) used as monotherapy, intolerance, or contraindication to at least one generic oral atypical antipsychotic therapy that has been used as adjunctive (i.e. add-on) to antidepressant therapy AND Vraylar must be used as adjunctive treatment to antidepressant therapy and not as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# VUMERITY - CAPSULE, DELAYED RELEASE (ENTERIC COATED)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member has a diagnosis of a relapsing form of multiple sclerosis, to include relapsing-remitting or active secondary progressive disease OR the member has a diagnosis of a clinically isolated syndrome (CIS).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## VYLOY - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on Vyloy (zolbetuximab- clzb).
Required Medical Information	Gastric or Gastroesophageal Junction Adenocarcinoma (GEJ): The member has a diagnosis of locally advanced unresectable or metastatic, human epidermal growth factor receptor 2 (HER2)-negative, gastric or gastroesophageal junction (GEJ) adenocarcinoma AND The disease is claudin (CLDN) 18.2 positive as determined by an FDA approved test AND Vyloy (zolbetuximab-clzb) will be used in combination with a fluoropyrimidine- (fluorouracil [5-FU], capecitabine) and platinum- containing chemotherapy as first-line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

#### **VYNDAMAX - CAPSULE**

	1
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cardiomyopathy of Transthyretin-Mediated Amyloidosis (ATTR-CM): Member has a history of NYHA Class I through III Heart Failure AND Member has a diagnosis of ATTR-CM defined as: Significant cardiac involvement (e.g. substantial ventricular wall thickening or elevated intra- cardiac filling pressures) on echocardiography or cardiac MRI and one of the following: Medical records indicate presence of transthyretin precursor protein confirmed on immunohistochemical analysis, scintigraphy, or mass spectrometry using Technescan PYP (PYP Screening) or Medical records indicate presence of amyloid deposits on analysis of biopsy specimens. The member does not have a history of any of the following: Liver Transplant, Heart Transplant without evidence of further amyloid deposits post-transplant, Left Ventricular Assist Device (LVAD), Current Pregnancy.
Age Restriction	
Prescriber Restriction	The member is being treated by a specialist (e.g. cardiologist).
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# VYVGART - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Generalized Myasthenia Gravis (gMG): The member has a diagnosis of generalized myasthenia gravis AND The presence of anti-acetylcholine receptor (AChR) antibodies has been confirmed AND The member is being treated by, or under the supervision of, a specialist (e.g. neurologist) experienced in the management of generalized myasthenia gravis AND The member has had previous treatment, contraindication, or intolerance to: Pyridostigmine AND at least 1 immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide). Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) - Vyvgart Hytrulo only: The member has a diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) AND the member is being treated by, or under the supervision of, a specialist (e.g. neurologist) experienced in the management of CIDP AND the member has had previous treatment with, or has a contraindication or intolerance to, an intravenous immune globulin (IVIG) or subcutaneous immune globulin (SCIG) product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## VYVGART HYTRULO - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Generalized Myasthenia Gravis (gMG): The member has a diagnosis of generalized myasthenia gravis AND The presence of anti-acetylcholine receptor (AChR) antibodies has been confirmed AND The member is being treated by, or under the supervision of, a specialist (e.g. neurologist) experienced in the management of generalized myasthenia gravis AND The member has had previous treatment, contraindication, or intolerance to: Pyridostigmine AND at least 1 immunosuppressive therapy (e.g., azathioprine, cyclosporine, mycophenolate mofetil, tacrolimus, methotrexate, cyclophosphamide). Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) - Vyvgart Hytrulo only: The member has a diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) AND the member is being treated by, or under the supervision of, a specialist (e.g. neurologist) experienced in the management of CIDP AND the member has had previous treatment with, or has a contraindication or intolerance to, an intravenous immune globulin (IVIG) or subcutaneous immune globulin (SCIG) product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## VYXEOS - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on Vyxeos (daunorubicin and cytarabine). Member has experienced disease progression on conventional daunorubicin and cytarabine regimen (e.g. "7+3")
Required Medical Information	Acute Myeloid Leukemia: The member has a diagnosis of therapy- related acute myeloid leukemia (t-AML) or AML with myelodysplasia- related changes (AML-MRC) AND one of the following applies: The member has newly diagnosed disease OR the member is using Vyxeos (daunorubicin and cytarabine) as post-remission therapy (if given in induction) OR the member is using Vyxeos (daunorubicin and cytarabine) as re-induction (if given in induction).
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA
Part B Prerequisite	0

#### WELIREG - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Welireg (belzutifan).
Required Medical Information	von Hippel Lindau VHL disease: The member has von Hippel Lindau (VHL) disease and the member does not require immediate surgery and The member requires treatment for: associated renal cell carcinoma (RCC) OR associated central nervous system hemangioblastomas OR pancreatic neuroendocrine tumors and Welireg (belzutifan) is administered as monotherapy. Reauthorization criteria: Physician attestation that the member has continued to receive a clinical benefit (e.g., response of lesions by imaging). Renal Cell Carcinoma (RCC). The member has advanced renal cell carcinoma AND The member failed to achieve treatment goals or has documented intolerance when previously treated with both of the following: programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor AND a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI) AND Welireg (belzutifan) is administered as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	VHL disease: Initial auth: 6 months duration. Reauth: plan year duration. RCC: Plan year duration.
Other Criteria	
Part B Prerequisite	0

#### **XALKORI - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members using Xalkori (crizotinib) for adjuvant therapy.
Required Medical Information	Non-small Cell Lung Cancer (NSCLC). The member has a diagnosis of metastatic or recurrent non-small cell lung cancer (NSCLC) and The member will be using Xalkori (crizotinib) as monotherapy and one of the following applies: The member has documented anaplastic lymphoma kinase (ALK)-positive NSCLC disease AND the member has a medical reason as to why Alecensa (alectinib) or Alunbrig (brigatinib) cannot be started or continued OR the member has disease which is ROS1 positive. Anaplastic large cell lymphoma (ALCL): The member has a diagnosis of relapsed or refractory, systemic ALCL AND the disease has documented ALK-positivity AND Xalkori (crizotinib) is given as monotherapy. Inflammatory myofibroblastic tumor (IMT): the member has a diagnosis of unresectable, recurrent, or refractory IMT AND the disease has documented ALK-positivity AND Xalkori (crizotinib) is given as monotherapy.
Age Restriction	ALCL: The member is greater than 1 year of age up to young adult (21 years of age). IMT: The member is greater than 1 year of age and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

## XATMEP - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members with disease progression on Xatmep (methotrexate) (applies to acute lymphoblastic leukemia only).
Required Medical Information	Acute Lymphoblastic Leukemia (ALL): The member has a diagnosis of acute lymphoblastic leukemia AND The member will be using Xatmep (methotrexate) as part of a multi-phase, combination chemotherapy maintenance regimen AND The member has had previous treatment or intolerance to generic methotrexate. Polyarticular Juvenile Idiopathic Arthritis (pJIA): The member has a diagnosis of active polyarticular juvenile idiopathic arthritis (pJIA) AND The member has had previous treatment or intolerance to generic methotrexate. BvsD Coverage Determination may also be required.
Age Restriction	The member is less than 18 years of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **XCOPRI - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: The member has a diagnosis of partial- onset (focal) seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **XCOPRI MAINTENANCE PACK - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: The member has a diagnosis of partial- onset (focal) seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **XCOPRI TITRATION PACK - TABLET, DOSE PACK**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: The member has a diagnosis of partial- onset (focal) seizures AND Member has been unable to achieve seizure control with at least TWO other drugs for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

#### **XDEMVY - DROPS**

	Oritoria Dataila
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Demodex blepharitis: Has a diagnosis of Demodex blepharitis AND Has collarettes present on more than 10 lashes on the upper eyelid upon slit lamp examination AND Has at least mild erythema of the upper eyelid margin AND Xdemvy (lotilaner) is prescribed by or in consultation with an optometrist or ophthalmologist.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## XGEVA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concurrent use of bisphosphonate therapy (e.g., zoledronic acid, pamidronate)
Required Medical Information	Osteolytic Bone Metastases of Solid Tumors. The member has a diagnosis of solid tumor cancer (such as breast cancer, prostate cancer, or other solid tumor). The member must have documented bone metastases. The member has experienced disease progression, intolerance or contraindication following treatment with zoledronic acid or pamidronate (disease progression, intolerance or contraindication following treatment with zoledronic acid or pamidronate (disease progression, intolerance or contraindication following treatment with pamidronate or zoledronic acid does not apply for prostate cancer). Multiple Myeloma: The member has a diagnosis of multiple myeloma AND the member has experienced disease progression, intolerance or contraindication following treatment with zoledronic acid or pamidronate. Giant Cell tumor of Bone: Diagnosis of giant cell tumor of bone. Hypercalcemia of malignancy: The member has hypercalcemia of malignancy, defined as an albumin-corrected calcium of greater than 12.5 mg/dL AND The member has had prior therapy, intolerance, or contraindication to intravenous bisphosphonate therapy (e.g. pamidronate or zoledronic acid).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	1

#### **XIFAXAN - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Traveler's diarrhea: Member must have traveler's diarrhea caused by non-invasive strains of Escherichia Coli AND Member's condition is not complicated by fever or blood in the stool AND Member has tried or cannot use ciprofloxacin, levofloxacin, or azithromycin. Hepatic encephalopathy prophylaxis: Member has had at least one overt episode of hepatic encephalopathy (HE) AND Xifaxan (rifaximin) is being used to reduce the risk of HE recurrence. Irritable bowel syndrome with diarrhea (IBS-D): Member has a diagnosis of Irritable bowel syndrome with diarrhea (IBS-D).
Age Restriction	Must be age 12 or older for Travelers Diarrhea, Age 18 or older for Hepatic encephalopathy prophylaxis and IBS-D.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## XOLAIR - AUTO-INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Chronic Idiopathic Urticaria. Member has a diagnosis of chronic idiopathic urticaria. Member has remained symptomatic despite at least 2 weeks of H1 antihistamine therapy, unless contraindicated. Member will continue to receive H1 antihistamine therapy while on Xolair, unless contraindicated. Moderate or Severe persistent asthma. The patient has a diagnosis of moderate or severe persistent asthma. The patient has evidence of specific allergic sensitivity confirmed by positive skin test (i.e. prick/puncture test) or blood test (i.e. RAST) for a specific IgE or in vitro reactivity to a perennial aeroallergen. Member must have baseline serum IgE greater than or equal to 30 IU/ml. The patient has inadequately controlled asthma despite the use of Inhaled Corticosteroids.
Age Restriction	The patient is 12 years of age or older for diagnosis of chronic idiopathic urticaria. The patient is 6 years of age or older for moderate to severe persistent asthma. The patient is 18 years of age or older for nasal polyps. The patient is 1 year or older for IgE Mediated Food Allergy.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Nasal Polyps: The member must meet all of the following criteria: have a diagnosis of nasal polyps (e.g., Chronic Rhinosinusitis with Nasal Polyposis [CRSwNP]) AND Xolair will be used in combination with a daily intranasal corticosteroid spray AND is unable to achieve adequate control of symptoms with maximum tolerated intranasal corticosteroid therapy. IgE Mediated Food Allergy: Member has been diagnosed with IgE mediated food allergy AND Member is using Xolair to reduce allergic reactions (Type I), including anaphylaxis, that may occur with accidental exposure to one of more foods AND Member is using in conjunction with food allergen avoidance.
Part B Prerequisite	0

#### **XOSPATA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Acute Myeloid Leukemia. The member has a diagnosis of acute myeloid leukemia AND The member has relapsed or refractory disease AND The member has documented FLT3 mutation positive disease AND The member will be using Xospata (gilteritinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration
Other Criteria	
Part B Prerequisite	0

#### **XPOVIO - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on Xpovio (selinexor).
Required Medical Information	Multiple Myeloma: The member has a diagnosis of multiple myeloma AND The member has received at least one prior therapy AND The member will be using Xpovio in combination with dexamethasone and bortezomib (unless documented intolerance/contraindication to corticosteroid) OR The member has a diagnosis of multiple myeloma AND The member has received at least four prior therapies AND The member's disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents and an anti-CD38 monoclonal antibody AND The member will be using Xpovio (selinexor) in combination with dexamethasone (unless documented intolerance/contraindication to corticosteroid). Diffuse large B-cell lymphoma: The member has a diagnosis of relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma AND The member has received at least two prior lines of systemic therapy AND The member will be using Xpovio (selinexor) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

#### XTANDI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Xtandi (enzalutamide).
Required Medical Information	Prostate Cancer (metastatic castration-resistant): The member has metastatic (stage IV) castration-resistant prostate cancer (CRPC). Prostate Cancer (non-metastatic castration-resistant): The member has a diagnosis of non-metastatic castration-resistant prostate cancer AND The member will use Xtandi (enzalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog). Prostate Cancer (metastatic castration-sensitive): the member has a diagnosis of metastatic castration-sensitive prostate cancer AND the member will use Xtandi (enzalutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or GnRH analog). Prostate Cancer (non-metastatic castration-sensitive): The member has a diagnosis of non-metastatic castration-sensitive): The member has a diagnosis of non-metastatic castration-sensitive): The member has a diagnosis of non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence at high risk for metastasis (biochemical recurrence at high risk for metastasis defined as prostate-specific antigen [PSA] doubling time less than or equal to 9 months, PSA greater than or equal to 1 ng/mL post radical prostatectomy, or screening PSA greater than or equal to 2 ng/mL above nadir post radiotherapy).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# YERVOY - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Melanoma: Concomitant Zelboraf (vemurafenib), Tafinlar (dabrafenib), Cotellic (cobimetnib) or Mekinist (trametinib) therapy AND The member has had progression of disease on adjuvant therapy with Yervoy (ipilimumab). MSI-H or dMMR: Disease progression while on or following previous anti-CTLA4-based combinations (e.g., Opdivo [nivolumab] with Yervoy [ipilimumab]). Hepatocellular carcinoma: Disease progression while on or following previous anti-CTLA-based combinations (e.g., Imjudo [tremelimumab-actl] with Imfinzi [durvalumab]).
Required Medical Information	Melanoma. The member has a diagnosis of unresectable or metastatic melanoma OR Adjuvant treatment of cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 millimeter who have undergone complete resection, including total lymphadenectomy. The member is naive to Yervoy (ipilimumab). The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. Melanoma - Reauthorization Criteria unresectable or metastatic. The member had stable disease, partial response or complete response for greater than 3 months following the completion of initial induction (completion of four cycles within a 16 week period. Members who were unable to tolerate or receive the complete induction regimen within 16 weeks of initiation will not receive approval). AND The member has progressive disease, necessitating reinduction therapy with Yervoy (ipilimumab). AND The member has an Eastern Cooperative Oncology Group (ECOG) performance status of 0-2. Reauth adjuvant treatment of cutaneous melanoma. The member has not had disease recurrence or unacceptable toxicity with Yervoy (ipilimumab) AND The total duration of treatment is less than 3 years AND The member has an ECOG performance status of 0-2. Renal Cell Carcinoma. The member has a diagnosis of advanced renal cell carcinoma (RCC) AND The member has predominant clear cell histology AND The member will be using Yervoy (ipilimumab) in combination with Opdivo (nivolumab) AND The member will be using for first line therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	4 Months Duration

## YERVOY - VIAL (ML)

Other Criteria	Microsatellite Instability-High (MSI-H) or Mismatch Repair Deficient (dMMR) Metastatic Colorectal Cancer. The member has a diagnosis of unresectable or metastatic colorectal cancer with documented microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) AND The member will be using Yervoy (ipilimumab) in combination with Opdivo (nivolumab). Hepatocellular carcinoma: The member has a diagnosis of hepatocellular carcinoma AND The member will be using Yervoy (ipilimumab) in combination with Opdivo (nivolumab). Non-small cell lung cancer (NSCLC) First Line Therapy: The member must have a diagnosis of metastatic non-small cell lung cancer (NSCLC) AND one of the following applies: Disease with PD-L1 expression greater than or equal to 1% with no EGFR or ALK genomic tumor aberrations and given as first line therapy AND Tumor expresses PD-L1 as determined by an FDA-approved test AND Will be used in combination with Opdivo (nivolumab) OR Disease with no EGFR or ALK genomic tumor aberrations and given as first line therapy AND Will be used in combination with Opdivo (nivolumab) AND Will be used in combination with two cycles of platinum doublet chemotherapy. Malignant pleural mesothelioma: The member has a diagnosis of unresectable malignant pleural mesothelioma AND The member will be using for first-line or subsequent treatment, if not administered first-line AND Yervoy (ipilimumab) will be used in combination with Opdivo (nivolumab). Esophageal Cancer (squamous cell carcinoma): the member has unresectable advanced, recurrent, or metastatic squamous cell carcinoma of the esophagus AND Yervoy will be given as first line treatment in combination with Opdivo.
Part B Prerequisite	0
	unresectable malignant pleural mesothelioma AND The member will using for first-line or subsequent treatment, if not administered first-li AND Yervoy (ipilimumab) will be used in combination with Opdivo (nivolumab). Esophageal Cancer (squamous cell carcinoma): the member has unresectable advanced, recurrent, or metastatic squam cell carcinoma of the esophagus AND Yervoy will be given as first lin treatment in combination with Opdivo.

## YESINTEK - VIAL (ML)

	1
PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe chronic plaque psoriasis (SC formulation only): The member must have a diagnosis of moderate to severe chronic plaque psoriasis AND The member has had prior therapy or intolerance to one or more oral systemic tretaments (e.g. methotrexate, cyclosporine) or contraindication to all conventional oral systemic treatments. Psoriatic arthritis (SC formulation only): The member must have a diagnosis of active psoriatic arthritis. Moderately to severely active Crohn's disease (IV and SC formulations). The member must have a diagnosis of moderately to severely active colitis (IV and SC formulations): The member must have a diagnosis of active ulcerative colitis (IV and SC formulations): The member must have a diagnosis of active ulcerative colitis (IV and SC formulations): The member must have a diagnosis of moderately to severely active ulcerative colitis.
Age Restriction	Moderate to severe chronic plaque psoriasis and psoriatic arthritis: The member must be 6 years of age or older. For all other indications: Must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## YONDELIS - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Yondelis (trabectedin)
Required Medical Information	Liposarcoma/Leiomyosarcoma: The member has unresectable or metastatic liposarcoma or leiomyosarcoma AND The member has received prior anthracycline (e.g., doxorubicin) containing regimen. Soft Tissue Sarcoma. Yondelis (trabectedin) will be used as monotherapy for palliative treatment and one of the following applies: The member has a diagnosis of unresectable or progressive retroperitoneal or intraabdominal soft tissue sarcoma OR the member has a diagnosis of angiosarcoma or rhabdomyosarcoma OR the member has a diagnosis stage IV soft tissue sarcoma of the extremity/superficial trunk, head/neck, or recurrent disease with disseminated metastases.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## ZALTRAP - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Zaltrap.
Required Medical Information	Metastatic Colorectal Cancer: The member has a diagnosis of metastatic colorectal cancer AND The member is using Zaltrap in combination with irinotecan or FOLFIRI (leucovorin, irinotecan, 5-fluorouracil) chemotherapy AND At least one of the following applies: Zaltrap is being used as second line therapy AND The member experienced disease progression or resistance with an Oxaliplatin containing regimen OR The member has unresectable metachronous metastases and has received previous adjuvant FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or CapeOX(capecitabine and oxaliplatin)
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## ZARXIO - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with filgrastim product or pegfilgrastim product (e.g., filgrastim, filgrastim-sndz, filgrastim-aafi, pegfilgrastim-jmbd, pegfilgrastim-cbqv) within seven days of pegfilgrastim dose.
Required Medical Information	Neutropenia in Myelodysplastic Syndromes. The member must have a diagnosis of neutropenia associated with myelodysplastic syndrome. Treatment of Febrile Neutropenia: The member must have a diagnosis of febrile neutropenia AND filgrastim product must be used in adjunct with appropriate antibiotics in high risk members. Febrile Neutropenia Prophylaxis: The member must have a diagnosis of non-myeloid malignancy (e.g., solid tumors) AND The member has received or will receive filgrastim product 24-72 hours after the administration of myelosuppressive chemotherapy AND The member must also meet ONE OR MORE of the following criteria: A risk of febrile neutropenia (FN) of greater than 20% based on current chemotherapy regimen (as listed in current ASCO and NCCN guidelines for myeloid growth factors) OR A risk of febrile neutropenia of 10-20% based on chemotherapy regimen, and at least ONE of the following risk factors apply OR A risk of febrile neutropenia of less than 10% based on chemotherapy regimen, and at least ONE of the following risk factors apply OR A risk of febrile neutropenia of less than 10% based on chemotherapy regimen, and at least TWO of the following risk factors apply: Prior chemotherapy or radiation therapy, Persistent neutropenia (defined as neutrophils/mcL and a predicted decline to less than or equal to 500 neutrophils/mcL over next 48 hours), Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2.0 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Previous neutropenic fever complication or dose-limiting neutropenic event from a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR As secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration

## ZARXIO - SYRINGE (ML)

Other Criteria	Febrile Neutropenia Prophylaxis, in members with acute myeloid leukemia receiving chemotherapy: The member must have a diagnosis Acute Myeloid Leukemia (AML). The member must be receiving either induction chemotherapy OR consolidation Chemotherapy AND The member is not administering filgrastim product earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy. Febrile Neutropenia Prophylaxis, In non-myeloid malignancies following Hematopoietic Stem Cell Transplant (HCST): The member must have had a Hematopoietic Stem Cell Transplant (HCST) (e.g. bone marrow transplant, peripheral-blood progenitor cell (PBPC) transplant) for a non- myeloid malignancy AND The member is not administering filgrastim product earlier than 24 hours after cytotoxic chemotherapy or within 24 hours before chemotherapy Harvesting of peripheral blood stem cells. The member must be scheduled for autologous peripheral-blood stem cell (PBSC) transplant, or donating stem cells for a possible future autologous transplant, or donating stem cells for an allogeneic or syngeneic PBSC transplant. Neutropenic disorder, chronic (Severe), Symptomatic: The member must have a diagnosis of congenital, cyclic, or idiopathic neutropenia. Neutropenia in AIDS patients. The member must have a diagnosis of AIDS with neutropenia. Treatment of Aplastic Anemia. The member must have a diagnosis of Aplastic Anemia. Treatment of Agranulocytosis. The member must have a diagnosis of congenital or drug induced agranulocytosis. Hematopoietic Syndrome of Acute radiation syndrome. The member has been acutely exposed to myelosuppressive doses of radiation.
Part B Prerequisite	0

## **ZEJULA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on or following PARP inhibitor therapy [e.g., Rubraca (rucaparib), Lynparza (olaparib), Zejula (niraparib)].
Required Medical Information	Epithelial Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer subsequent line maintenance therapy: The member has a diagnosis of recurrent epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer AND The member has been treated with at least two prior lines of platinum based chemotherapy AND The member is in complete or partial response to their last platinum regimen AND The member will utilize Zejula (niraparib) as a monotherapy* AND *Discontinue Bevacizumab product before initiating maintenance therapy with Zejula. Advanced Ovarian Cancer, Fallopian Tube, or Peritoneal Cancer First Line Maintenance Therapy: member has a diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer AND member is in complete response or partial response to first line treatment with platinum based chemotherapy AND member will utilize Zejula (niraparib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## **ZELBORAF - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Tafinlar (dabrafenib), Mekinist (trametinib), Braftovi (encorafenib), or Mektovi (binimetinib). Members that have experienced disease progression while on Zelboraf (vemurafenib). Members that have experienced disease progression while on prior anti- BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Tafinlar (dabrafenib) with Mekinst (trametinib)].
Required Medical Information	Melanoma: The member has a diagnosis of Unresectable or Stage IV Metastatic melanoma. The member has a documented BRAF V600 activating mutation. The member will be using Zelboraf (vemurafenib) as monotherapy OR in combination with Cotellic (cobimetnib). Erdheim- Chester Disease: The member has a diagnosis of Erdheim-Chester Disease AND The member has a documented BRAF V600 mutation AND The member will be using Zelboraf (vemurafenib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	0

# ZEMAIRA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	IgA deficient members or presence of antibodies against IgA.
Required Medical Information	The member must meet ALL of the following criteria: Diagnosis of congenital alpha1-antitrypsin deficiency with clinically evident emphysema and chronic replacement therapy is needed AND Has an alpha1-antitrypsin phenotype of PiZZ, PiZ(null), or PI (null, null) or phenotypes associated with serum alpha 1-antitrypsin concentrations of less than 57mg/dL if/when measured by laboratories using nephelometry instead of radial immunodiffusion. Otherwise, a deficiency is shown at 80mg/dL. (These products should not be used in individuals with the PiMZ or PiMS phenotypes of alpha1-antitrypsin deficiency because these individuals appear to be at small risk of developing clinically evident emphysema.)
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

# ZEPZELCA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Zepzelca (lurbinectedin).
Required Medical Information	Small cell lung cancer: The member has a diagnosis of metastatic small cell lung cancer AND The member had progression on or after treatment with platinum-based chemotherapy AND Zepzelca (lurbinectedin) will be used as a single agent.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# ZEVALIN (Y-90) - KIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have received previous radioimmunotherapy with Zevalin (ibritumomab tiuxetan).
Required Medical Information	The member has relapsed or refractory, low-grade or follicular B-cell non-Hodgkin's lymphoma (NHL) OR The member has previously untreated (radioimmunotherapy) follicular NHL and achieved a partial or complete response to first-line chemotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	1 month Duration
Other Criteria	
Part B Prerequisite	0

# ZIIHERA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression Ziihera (zanidatamab- hrii).
Required Medical Information	Biliary Tract Cancer (BTC): The member has a diagnosis of unresectable or metastatic biliary tract cancer (BTC) AND The disease is documented as human epidermal growth factor receptor 2 (HER2)-positive [IHC 3+], as determined by an FDA approved test AND The member has previously been treated with at least one prior line of therapy (i.e., gemcitabine-based regimen) AND Ziihera (zanidatamab-hrii) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

# ZIRABEV - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Used in lung cancer members that have small cell or squamous cell disease, recent hemoptysis, history of bleeding, continuing anticoagulation, or as a single agent (unless maintenance as described in Coverage Determinations). Should not be initiated in members with recent hemoptysis. Should not be used in members who experience a severe arterial thromboembolic event. Should not be used in members with gastrointestinal perforation. Bevacizumab should not be used in members with fistula formation involving internal organs. Bevacizumab should not be used in members experiencing a hypertensive crisis or hypertensive encephalopathy. Bevacizumab should not be used for at least 28 days following major surgery or until surgical incision is fully healed. Bevacizumab may not be used in conjunction with Vectibix. Bevacizumab may not be used in the adjuvant or neoadjuvant setting (except in epithelial ovarian, fallopian tube, or primary peritoneal cancer adjuvant setting). Bevacizumab should not be continued or restarted after disease progression with the exception of metastatic colorectal cancer.

# ZIRABEV - VIAL (ML)

Avastin (bevacizumab), Alymsys (bevacizumab- maly) and Vegzelma (bevacizumab-adcd) oncology requests: must have an intolerance or contraindication with Mvasi or Zirabev. Metastatic colorectal cancer: metastatic colorectal cancer AND 1 of the following apply: using bevacizumab in combo with fluoropyrimidine (e.g., 5- fluorouracil or capecitabine) based chemo for 1st or 2nd-line therapy OR in combo with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin- based chemo for 2nd-line therapy in patients who have progressed on 1st-line bevacizumab-containing regimens. Non-small cell lung cancer (non-squamous cell histology). NSCLC with non-squamous cell histology AND using bevacizumab in combo with cisplatin or carboplatin based regimens for unresectable, locally advanced, recurrent, or metastatic NSCLC AND 1 of the following apply: for 1st line therapy OR as subsequent therapy immediately after 1 of the following situations: EGFR mutation-positive tumors after prior therapy [if cytotoxic therapy not previously given] OR ALK-positive tumors after prior therapy [if cytotoxic therapy not previously given] OR Pembrolizumab (with PD-L1 expression of greater than or equal to 1%) administered as 1st line therapy and EGFR, ALK, BRAF V600E, and ROS1 negative tumors (if cytotoxic therapy not previously given) OR has BRAF V600E positive disease (if cytotoxic therapy not previously given) OR using bevacizumab as single-agent continuation maintenance therapy if bevacizumab was used as 1st line treatment for recurrence or metastasis OR has disease with no EGFR or ALK genomic tumor aberrations AND bevacizumab will be given in combo with carboplatin and paclitaxel and Tecentriq as 1st line therapy followed by maintenance therapy with combo Tecentriq and bevacizumab. Hepatocellular carcinoma: unresectable or metastatic HCC AND used will be used as 1st line therapy in combo with Tecentriq.
Licensed Practitioner
Plan Year Duration

## ZIRABEV - VIAL (ML)

#### Other Criteria

Metastatic breast cancer (Effectiveness based on improvement in progression-free survival. No data available demonstrating improvement in disease-related symptoms or survival with bevacizumab). Member has metastatic HER-2 negative breast cancer AND is using bevacizumab in combo with paclitaxel. Recurrent Ovarian Cancer. Bevacizumab is being used to treat recurrent or persistent ovarian cancer for 1 of the following situations: in combo with liposomal doxorubicin or weekly paclitaxel or topotecan for platinum resistant disease or as monotherapy or in combo with carboplatin and gemcitabine for platinum sensitive disease. Stage IV/Metastatic (Unresectable) RCC. Member has RCC and is using bevacizumab to treat stage IV unresectable kidney cancer in combo with interferon alpha OR is using bevacizumab as systemic therapy for nonclear cell histology. Recurrent Primary CNS Tumor (including Glioblastoma multiforme). Diagnosis of progressive or recurrent glioblastoma or anaplastic glioma AND Bevacizumab is being used as a single agent or in combo with irinotecan, carmustine, lomustine or temozolomide. Member does not have a CNS hemorrhage. Soft Tissue Sarcoma. Diagnosis of angiosarcoma and bevacizumab is being used as a single agent OR member has a diagnosis of solitary fibrous tumor and hemangiopericytoma and bevacizumab is being used in combo with temozolomide. Macular Retinal Edema. Avastin is being used to treat central or branch retinal vein occlusion with macular retinal edema. Cervical Cancer: member has recurrent, or metastatic cervical cancer AND Bevacizumab will be used in combo with paclitaxel and cisplatin or carboplatin and paclitaxel or paclitaxel and topotecan as first line therapy. Endometrial Cancer: progressive endometrial cancer AND Bevacizumab will be used as a single-agent. Malignant Pleural Mesothelioma. Diagnosis of unresectable malignant pleural mesothelioma and bevacizumab will be used in combo with cisplatin and pemetrexed followed by bevacizumab monotherapy for maintenance therapy (for responders). Epithelial ovarian, fallopian tube, or primary peritoneal cancer: Diagnosis of epithelial ovarian, fallopian tube or primary peritoneal cancer AND has Stage III or IV disease AND bevacizumab is initially being given in combo with carboplatin and paclitaxel after initial surgical resection followed by bevacizumab monotherapy OR advanced epithelial ovarian, fallopian tube or primary peritoneal cancer AND disease is associated with homologous recombination deficiency (HRD) positive status defined by either: a deleterious or suspected deleterious BRCA mutation OR genomic instability as defined by FDA approved test AND Member is in complete response or partial response to 1st line treatment with platinum-based chemo AND Bevacizumab is given in combo with Lynparza. Age Related Macular Degeneration (Avastin requests only). Diabetic Macular Edema (Avastin requests only). 0 Prerequisite

Part B

## zoledronic acid-mannitol-water - IV SOLUTION, PIGGYBACK, BOTTLE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Osteoporosis: The member has a diagnosis of osteoporosis. Has new fractures or significant loss of bone mineral density despite previous treatment, contraindication, or intolerance to any other oral OR IV bisphosphonate. Osteoporosis Prophylaxis in postmenopausal members: The member is postmenopausal. Has new fractures or significant loss of bone mineral density despite previous treatment, contraindication, or intolerance to any other oral OR IV bisphosphonate. Glucocorticoid induced Osteoporosis in men and women taking systemic glucocorticoids: Diagnosis of glucocorticoid induced osteoporosis or is either initiating or continuing systemic glucocorticoids with a daily dosage equivalent of 7.5 mg or greater of prednisone and is expected to remain on glucocorticoids for at least 12 months AND has new fractures or significant loss of bone mineral density despite previous treatment, contraindication, or intolerance to any other oral OR IV bisphosphonate . Paget's Disease: Diagnosis of Paget's disease. The member has continued elevation(s) in serum alkaline phosphatase (SAP) of two times or higher than the upper limit of normal despite previous treatment, contraindication, or intolerance to any other oral OR IV bisphosphonate. And the member: Is symptomatic OR is at risk for complications from their disease, to induce remission, or to normalize serum alkaline phosphatase. Brand Reclast request only: Members must have previous treatment, contraindication, or intolerance to generic Zoledronic acid (generic Reclast).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## **ZOLINZA - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Cutaneous T-Cell Lymphoma (CTCL). The member has a diagnosis of progressive, persistent, or recurrent disease or The member will be using Zolinza (vorinostat) as primary treatment or adjuvant therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## ZONISADE - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Partial-Onset (Focal) Seizures: Member has a diagnosis of partial-onset (focal) seizures AND Zonisade (zonisamide) will be used in combination with at least one other drug for controlling partial-onset seizures AND Member has tried or cannot use zonisamide capsules AND at least one other drug for controlling partial-onset seizures (e.g., levetiracetam, lamotrigine, carbamazepine, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	0

## ZTALMY - SUSPENSION, ORAL (FINAL DOSE FORM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Seizures associated with Cyclin-dependent Kinase-Like 5 (CDKL5) Deficiency Disorder (CDD): the member has a diagnosis of cyclin- dependent kinase-like 5 CDKL5) deficiency disorder (CDD).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	0

## **ZURZUVAE - CAPSULE**

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Postpartum Depression. The member has a documented diagnosis of a major depressive episode as defined by DSM-5 criteria and severity as determined by an appropriate depression rating scale (e.g. HAM-D, MADRS, PHQ-9) with onset of symptoms in the third trimester of pregnancy or within 4 weeks of delivery AND For the current major depressive episode, the member has had prior treatment, contraindication, or intolerance to an antidepressant other than zuranolone or brexanolone OR Physician attests with documentation that the severity of the depression would place the health of the mother or infant at significant risk AND The member will be receiving Zurzuvae therapy no later than one year postpartum AND The member will be receiving no more than one 14-day course of treatment with Zurzuvae for the current episode of postpartum depression.
Age Restriction	The member is at least 18 years of age.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	30 day duration
Other Criteria	
Part B Prerequisite	0

## **ZYDELIG - TABLET**

PA Criteria	Criteria Details	
Off-Label Uses		
Exclusion Criteria	The member has experienced disease progression while on or following a PI3K inhibitor (e.g. idelalisib, copanlisib).	
Required Medical Information	Chronic Lymphocytic Leukemia (CLL): The member must have a diagnosis of relapsed OR refractory chronic lymphocytic leukemia (CLL).	
Age Restriction		
Prescriber Restriction	Licensed Practitioner	
Coverage Duration	Plan Year Duration	
Other Criteria		
Part B Prerequisite	0	

## **ZYKADIA - TABLET**

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	NA
Required Medical Information	Non-small Cell Lung Cancer (NSCLC): The member has a diagnosis of metastatic and documented anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) AND the member has a medical reason as to why Alecensa (alectinib) OR Alunbrig (brigatinib) cannot be started or continued AND member will be using Zykadia (ceritinib) as monotherapy.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	NA
Part B Prerequisite	0

## ZYNLONTA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	NA
Exclusion Criteria	Member experienced disease progression on Zynlonta (loncastuximab tesirine-Ipyl).
Required Medical Information	B-cell Lymphoma: The member has a diagnosis of one of the following: diffuse large B-cell lymphoma (DLBCL) otherwise not specified, DLBCL arising from a low grade lymphoma (e.g. follicular lymphoma) OR a diagnosis of high-grade B-cell lymphoma (HGBL) not otherwise specified or with translocations AND The member has relapsed or refractory disease AND The member has had two or more lines of systemic therapy AND The member will be using Zynlonta as a single agent.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	NA
Part B Prerequisite	0

# ZYNYZ - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Merkel Cell Carcinoma: The member has a diagnosis of recurrent locally advanced or metastatic merkel cell carcinoma AND Zynyz (retifanlimab- dlwr) will be used as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six months duration
Other Criteria	
Part B Prerequisite	0

The following drugs are subject to a Medicare Part B or D authorization depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.

### PART B VERSUS PART D

#### **Products Affected**

• Akunzoo (notupitant) 200 mg 0 5 mg canculo	• Anzamat 50 MC: tablat
Akynzeo (netupitant) 300 mg-0.5 mg capsule	
• aprepitant 125 mg (1)-80 mg (2) capsules in a dose pack	<ul> <li>aprepitant 125 MG; 125 mg (1)- 80 MG (2);</li> <li>40 MG; 80 MG; capsule</li> </ul>
Astagraf XL 0.5 MG; 1 MG; 5 MG; capsule,extended release	<ul> <li>Azasan 100 MG; 75 MG; tablet</li> </ul>
• azathioprine 100 MG; 50 MG; 75 MG; tablet	<ul> <li>CellCept 200 MG/ML; 250 MG; 500 MG; capsule</li> </ul>
<ul> <li>CellCept 200 MG/ML; 250 MG; 500 MG; oral suspension</li> </ul>	<ul> <li>CellCept 200 MG/ML; 250 MG; 500 MG; tablet</li> </ul>
CellCept Intravenous 500 MG; intravenous solution	<ul> <li>chlorpromazine 10 MG; 25 MG; tablet</li> </ul>
<ul> <li>Compazine 10 MG; 5 MG; tablet</li> </ul>	<ul> <li>cyclophosphamide 25 MG; 50 MG; capsule</li> </ul>
<ul> <li>cyclophosphamide 25 MG; 50 MG; tablet</li> </ul>	<ul> <li>cyclosporine 100 MG; 25 MG; capsule</li> </ul>
<ul> <li>cyclosporine modified 100 MG; 100 MG/ML;</li> <li>25 MG; 50 MG; capsule</li> </ul>	<ul> <li>cyclosporine modified 100 MG; 100 MG/ML;</li> <li>25 MG; 50 MG; oral solution</li> </ul>
<ul> <li>dronabinol 10 MG; 2.5 MG; 5 MG; capsule</li> </ul>	• Emend 125 mg (1)- 80 MG (2); 125 mg (25 mg/ ML FINAL CONC.); 80 MG; capsule
• Emend 125 mg (1)-80 mg (2) capsules in a dose pack	<ul> <li>Emend 125 mg (25 mg/mL final conc.) oral suspension</li> </ul>
<ul> <li>Envarsus XR 0.75 MG; 1 MG; 4 MG; tablet,extended release</li> </ul>	<ul> <li>everolimus (immunosuppressive) 0.25 MG;</li> <li>0.5 MG; 0.75 MG; 1 MG; tablet</li> </ul>
<ul> <li>Gengraf 100 MG; 100 MG/ML; 25 MG; capsule</li> </ul>	Gengraf 100 MG; 100 MG/ML; 25 MG; oral solution
	•
capsule	solution
<ul><li>capsule</li><li>granisetron HCl 1 MG; tablet</li></ul>	solution <ul> <li>Imuran 50 MG; tablet</li> </ul>
<ul><li>capsule</li><li>granisetron HCl 1 MG; tablet</li><li>Jylamvo 2 MG/ML; oral solution</li></ul>	<ul><li>solution</li><li>Imuran 50 MG; tablet</li><li>Marinol 10 MG; 2.5 MG; 5 MG; capsule</li></ul>
<ul> <li>capsule</li> <li>granisetron HCl 1 MG; tablet</li> <li>Jylamvo 2 MG/ML; oral solution</li> <li>Medrol 16 MG; 2 MG; 4 MG; 8 MG; tablet</li> <li>methylprednisolone 16 MG; 32 MG; 4 MG; 8</li> </ul>	<ul> <li>solution</li> <li>Imuran 50 MG; tablet</li> <li>Marinol 10 MG; 2.5 MG; 5 MG; capsule</li> <li>methotrexate sodium 2.5 MG; tablet</li> </ul>
<ul> <li>capsule</li> <li>granisetron HCl 1 MG; tablet</li> <li>Jylamvo 2 MG/ML; oral solution</li> <li>Medrol 16 MG; 2 MG; 4 MG; 8 MG; tablet</li> <li>methylprednisolone 16 MG; 32 MG; 4 MG; 8 MG; tablet</li> <li>mycophenolate 500 MG; intravenous</li> </ul>	<ul> <li>solution</li> <li>Imuran 50 MG; tablet</li> <li>Marinol 10 MG; 2.5 MG; 5 MG; capsule</li> <li>methotrexate sodium 2.5 MG; tablet</li> <li>Millipred 5 MG; tablet</li> <li>mycophenolate mofetil 200 MG/ML; 250</li> </ul>
<ul> <li>capsule</li> <li>granisetron HCl 1 MG; tablet</li> <li>Jylamvo 2 MG/ML; oral solution</li> <li>Medrol 16 MG; 2 MG; 4 MG; 8 MG; tablet</li> <li>methylprednisolone 16 MG; 32 MG; 4 MG; 8 MG; tablet</li> <li>mycophenolate 500 MG; intravenous solution</li> <li>mycophenolate mofetil 200 MG/ML; 250</li> </ul>	<ul> <li>solution</li> <li>Imuran 50 MG; tablet</li> <li>Marinol 10 MG; 2.5 MG; 5 MG; capsule</li> <li>methotrexate sodium 2.5 MG; tablet</li> <li>Millipred 5 MG; tablet</li> <li>mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; capsule</li> <li>mycophenolate mofetil 200 MG/ML; 250</li> </ul>

capsule Neoral 100 MG; 100 MG/ML; 25 MG; oral ondansetron 16 MG; 4 MG; 8 MG; solution disintegrating tablet ondansetron HCI 4 MG; 4 MG/5 ML; 8 MG; ondansetron HCI 4 MG; 4 MG/5 ML; 8 MG; oral solution tablet Orapred ODT 10 MG; 15 MG; 30 MG; Pediapred 5 mg base/5 mL (6.7 MG/5 ML); disintegrating tablet oral solution prednisolone 10 MG; 10 MG/5 ML; 15 MG; prednisolone 15 MG/5 ML; 5 MG; oral 15 mg/5 mL (3 MG/ML); 15 MG/5 ML (5 ML); solution 20 mg/5 mL (4 MG/ML); 25 ma/5 mL (5 MG/ML); 30 MG; 5 mg base/5 mL (6.7 MG/5 ML); disintegrating tablet • prednisolone 15 MG/5 ML; 5 MG; tablet prednisolone sodium phosphate 10 MG; 10 MG/5 ML; 15 MG; 15 mg/5 mL (3 MG/ML); 15 MG/5 ML (5 ML); 20 mg/5 mL (4 MG/ML); 25 mg/5 mL (5 MG/ML); 30 MG; 5 mg base/5 mL (6.7 MG/5 ML); oral soln prednisolone sodium phosphate 10 MG; 10 prednisone 1 MG; 10 MG; 2.5 MG; 20 MG; 5 MG/5 ML; 15 MG; 15 mg/5 mL (3 MG/ML); 15 MG; 5 MG/5 ML; 50 MG; oral solution MG/5 ML (5 ML); 20 mg/5 mL (4 MG/ML); 25 mg/5 mL (5 MG/ML); 30 MG; 5 mg base/5 mL (6.7 MG/5 ML); oral solution prednisone 1 MG; 10 MG; 2.5 MG; 20 MG; 5
 Prednisone Intensol 5 MG/ML; oral MG; 5 MG/5 ML; 50 MG; tablet concentrate prochlorperazine maleate 10 MG; 5 MG; Prograf 0.2 MG; 0.5 MG; 1 MG; 5 MG; tablet capsule Prograf 0.2 MG; 0.5 MG; 1 MG; 5 MG; oral Rapamune 0.5 MG; 1 MG; 1 MG/ML; 2 MG; granules in packet oral solution • Rapamune 0.5 MG; 1 MG; 1 MG/ML; 2 MG; Rayos 1 MG; 2 MG; 5 MG; tablet, delayed tablet release Sandimmune 100 MG; 100 MG/ML; 25 MG; Sandimmune 100 MG; 100 MG/ML; 25 MG; oral solution capsule sirolimus 0.5 MG; 1 MG; 1 MG/ML; 2 MG; sirolimus 0.5 MG; 1 MG; 1 MG/ML; 2 MG; oral solution tablet tacrolimus 0.5 MG; 1 MG; 5 MG; capsule, Syndros 5 MG/ML; oral solution immediate-release tacrolimus XL 0.5 MG; 1 MG; 5 MG; Trexall 10 MG; 15 MG; 5 MG; 7.5 MG; tablet capsule, extended release 24 hr trimethobenzamide 300 MG; capsule Varubi 90 MG; tablet Veripred 20 20 mg/5 mL (4 MG/ML); oral Xatmep 2.5 MG/ML; oral solution solution Zortress 0.25 MG; 0.5 MG; 0.75 MG; 1 MG; tablet

Neoral 100 MG; 100 MG/ML; 25 MG;

Myhibbin 200 MG/ML; oral suspension

### Multi-Language Insert

#### Multi-language Interpreter Services

**English:** We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at 1-877-320-1235 (TTY: 711). Someone who speaks English can help you. This is a free service.

**Spanish:** Tenemos servicios de intérprete sin costo alguno para responder cualquier pregunta que pueda tener sobre nuestro plan de salud o medicamentos. Para hablar con un intérprete, por favor llame al 1-877-320-1235 (TTY: 711). Alguien que hable español le podrá ayudar. Este es un servicio gratuito.

**Chinese Mandarin:** 我们提供免费的翻译服务,帮助您解答关于健康或药物保险的任何疑问。如果 您需要此翻译服务,请致电 1-877-320-1235 (听障专线:711)。我们的中文工作人员很乐意帮助您。 这是一项免费服务。

Chinese Cantonese: 您對我們的健康或藥物保險可能存有疑問,為此我們提供免費的翻譯服務。如 需翻譯服務,請致電 1-877-320-1235 (聽障專線: 711)。我們講中文的人員將樂意為您提供幫助。這 是一項免費服務。

**Tagalog:** Mayroon kaming libreng serbisyo sa pagsasaling-wika upang masagot ang anumang mga katanungan ninyo hinggil sa aming planong pangkalusugan o panggamot. Upang makakuha ng tagasaling-wika, tawagan lamang kami sa 1-877-320-1235 (TTY: 711). Maaari kayong tulungan ng isang nakakapagsalita ng Tagalog. Ito ay libreng serbisyo.

**French:** Nous proposons des services gratuits d'interprétation pour répondre à toutes vos questions relatives à notre régime de santé ou d'assurance-médicaments. Pour accéder au service d'interprétation, il vous suffit de nous appeler au 1-877-320-1235 (TTY: 711). Un interlocuteur parlant Français pourra vous aider. Ce service est gratuit.

**Vietnamese:** Chúng tôi có dịch vụ thông dịch miễn phí để trả lời các câu hỏi về chương sức khỏe và chương trình thuốc men. Nếu quí vị cần thông dịch viên xin gọi 1-877-320-1235 (TTY: 711) sẽ có nhân viên nói tiếng Việt giúp đỡ quí vị. Đây là dịch vụ miễn phí.

**German:** Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelplan. Unsere Dolmetscher erreichen Sie unter 1-877-320-1235 (TTY: 711). Man wird Ihnen dort auf Deutsch weiterhelfen. Dieser Service ist kostenlos.

Korean: 당사는 의료 보험 또는 약품 보험에 관한 질문에 답해 드리고자 무료 통역 서비스를 제공하고 있습니다 . 통역 서비스를 이용하려면 전화 1-877-320-1235 (TTY: 711) 번으로 문의해 주십시오 . 한국어를 하는 담당자가 도와 드릴 것입니다 . 이 서비스는 무료로 운영됩니다 . **Russian:** Если у вас возникнут вопросы относительно страхового или медикаментного плана, вы можете воспользоваться нашими бесплатными услугами переводчиков. Чтобы воспользоваться услугами переводчика, позвоните нам по телефону 1-877-320-1235 (TTY: 711). Вам окажет помощь сотрудник, который говорит по-русски. Данная услуга бесплатная.

Arabic: إننا نقدم خدمات المترجم الفوري المجانية للإجابة عن أي أسئلة تتعلق بخطتنا الصحية أو خطة الأدوية الموصوفة لدينا. للحصول على مترجم فوري، ليس عليك سوى الاتصال بنا على (TTY: 711) 1235-320-1877. سيقوم شخص ما يتحدث العربية بمساعدتك. هذه خدمة مجانية.

**Hindi:** हमारे स्वास्थ्य या दवा की योजना के बारे में आपके किसी भी प्रश्न के जवाब देने के लिए हमारे पास मुफ्त दुभाषिया सेवाएँ उपलब्ध हैं. एक दुभाषिया प्राप्त करने के लिए, बस हमें 1-877-320-1235 (TTY: 711) पर फोन करें. कोई व्यक्ति जो हिन्दी बोलता है आपकी मदद कर सकता है. यह एक मुफ्त सेवा है.

**Italian:** È disponibile un servizio di interpretariato gratuito per rispondere a eventuali domande sul nostro piano sanitario e farmaceutico. Per un interprete, contattare il numero 1-877-320-1235 (TTY: 711). Un nostro incaricato che parla Italianovi fornirà l'assistenza necessaria. È un servizio gratuito.

**Portuguese:** Dispomos de serviços de interpretação gratuitos para responder a qualquer questão que tenha acerca do nosso plano de saúde ou de medicação. Para obter um intérprete, contacte-nos através do número 1-877-320-1235 (TTY: 711). Irá encontrar alguém que fale o idioma Português para o ajudar. Este serviço é gratuito.

**French Creole:** Nou genyen sèvis entèprèt gratis pou reponn tout kesyon ou ta genyen konsènan plan medikal oswa dwòg nou an. Pou jwenn yon entèprèt, jis rele nou nan 1-877-320-1235 (TTY: 711). Yon moun ki pale Kreyòl kapab ede w. Sa a se yon sèvis ki gratis.

**Polish:** Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język polski, należy zadzwonić pod numer 1-877-320-1235 (TTY: 711). Ta usługa jest bezpłatna.

Japanese:当社の健康保険と処方薬プランに関するご質問にお答えするために、無料の通訳サービスを ご用意しています。通訳をご用命になるには、1-877-320-1235 (TTY:711) にお電話ください。日本語 を話す者が支援いたします。これは無料のサービスです。