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#### Prior Authorization Criteria

Effective 02/01/2026

## abiraterone - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prostate Cancer: Members with severe hepatic impairment (Child-Pugh Class C).
Required Medical Information	Prostate Cancer: One of the following applies: The member has metastatic castration-resistant prostate cancer (mCRPC) or The member has a diagnosis of castration-sensitive prostate cancer (CSPC) and The member will be using abiraterone acetate in combination with a corticosteroid (prednisone, dexamethasone) and the member will use abiraterone in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## abirtega - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prostate Cancer: Members with severe hepatic impairment (Child-Pugh Class C).
Required Medical Information	Prostate Cancer: One of the following applies: The member has metastatic castration-resistant prostate cancer (mCRPC) or The member has a diagnosis of castration-sensitive prostate cancer (CSPC) and The member will be using abiraterone acetate in combination with a corticosteroid (prednisone, dexamethasone) and the member will use abiraterone in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## ADALIMUMAB-ADAZ - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). Psoriatic Arthritis: Diagnosis of 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.</p> <p>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. 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.</p> <p>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.</p>
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 - PEN INJECTOR (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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). Psoriatic Arthritis: Diagnosis of 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.</p> <p>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. 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.</p> <p>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.</p>
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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). Psoriatic Arthritis: Diagnosis of 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. 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.</p>
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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). Psoriatic Arthritis: Diagnosis of 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.</p> <p>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. 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.</p> <p>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.</p>
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	

## ADEMPAS - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## ALECENSA - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Non-Small Cell Lung Cancer (Adjuvant) only: The member exceeds two years of total Alecensa (alectinib) treatment and member has experienced disease progression while on Alecensa (alectinib).
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 (Adjuvant): 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 HCl, desipramine), or Xifaxan.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## ALUNBRIG - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## apomorphine - CARTRIDGE (ML)

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 Apokyn (apomorphine) 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	

## ARCALYST - VIAL (EA)

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 Cryopyrin-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	

## 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	

## 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	

## 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	

## AUGTYRO - CAPSULE

PA Criteria	Criteria Details
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	

## AUSTEDO - TABLET

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	

## 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	

## 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	

## 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	

## AYVAKIT - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member experiences disease progression on Ayvakit (avapritinib). [Applicable to all indications except Gastrointestinal stromal tumor (GIST)]
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 Ayvakit is not recommended for the treatment of members with AdvSM with platelet counts of less than 50 X 10 <sup>9</sup> /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 10 <sup>9</sup> /L AND Ayvakit (avapritinib) is administered as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	

## 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	

## BENLYSTA - AUTO-INJECTOR (ML)

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 IU/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 have a diagnosis of active lupus nephritis AND the member must be utilizing Benlysta in combination with standard therapy (e.g. corticosteroids with mycophenolate or cyclophosphamide).
Age Restriction	The member must be 5 years of age or older for Lupus Nephritis and Systemic Lupus Erythematosus (SLE).
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 (ropginterferon 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 (ropginterferon 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	

## 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	

## 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	

## 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). 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 (binimetine). Colorectal Cancer : 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 FOLFOX (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 (binimetine).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## brivaracetam - 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 has been unable to achieve seizure control with levetiracetam AND at least ONE other drug for controlling partial-onset seizures (e.g., lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## BRIVIACT - 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 has been unable to achieve seizure control with levetiracetam AND at least ONE other drug for controlling partial-onset seizures (e.g., lamotrigine, carbamazepine, zonisamide, divalproex, gabapentin or topiramate).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## **buprenorphine - PATCH, TRANSDERMAL WEEKLY**

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PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Moderate to severe pain: Has persistent (non-acute) pain that requires around the clock treatment for an extended period AND Has pain severe enough to require an opioid pain medication AND previous trials of alternative treatments (e.g., non-opioid analgesics) have been inadequate AND Has had previous treatment, contraindication, or intolerance to one of the following: immediate-release opioid (i.e., oxycodone, hydromorphone, or morphine) OR extended-release opioid (i.e., oxycodone, hydromorphone, or morphine).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 (cabozantinib) as monotherapy OR the member will be using Cabometyx (cabozantinib) 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	

## 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 cream/ointment).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## CAPLYTA - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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.</p> <p>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.</p> <p>Major Depressive Disorder: The member has a clinical diagnosis of major depressive disorder (MDD) AND The member has had previous treatment, contraindication, or intolerance to at least one antidepressant used as monotherapy for MDD AND The member has had previous treatment, contraindication, or intolerance to at least one generic atypical antipsychotic therapy that has been used as an adjunct (i.e., add-on) to antidepressant therapy AND Caplyta (lumateperone) will be used as adjunctive treatment to antidepressant therapy and not as monotherapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 oncocytic carcinoma or papillary carcinoma AND unresectable recurrent or persistent locoregional disease or metastatic disease.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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	

## clobazam - TABLET

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	

## **clozapine - TABLET,DISINTEGRATING**

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PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must be using clozapine ODT or Versacloz (clozapine oral solution) for treatment-resistant schizophrenia. The member must have had prior therapy or intolerance to generic clozapine tablets.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## COSENTYX - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, Rinvoq, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq. 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 two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz] and Rinvoq. 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 AND The member must have failed to achieve symptom control after previous treatment with a preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz].</p>
Age Restriction	<p>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.</p>
Prescriber Restriction	Licensed Practitioner

## COSENTYX - SYRINGE (ML)

Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, Rinvoq, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq. 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 two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz] and Rinvoq. 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 AND The member must have failed to achieve symptom control after previous treatment with a preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz].</p>
Age Restriction	<p>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.</p>
Prescriber Restriction	Licensed Practitioner

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

Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## COSENTYX PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, Rinvoq, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq. 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 two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz] and Rinvoq. 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 AND The member must have failed to achieve symptom control after previous treatment with a preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz].</p>
Age Restriction	<p>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.</p>
Prescriber Restriction	Licensed Practitioner

## COSENTYX PEN - PEN INJECTOR (ML)

Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, Rinvoq, preferred ustekinumab product (i.e., Stelara, Orlumia, Yesintek), or Tremfya. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq. 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 two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz] and Rinvoq. 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 AND The member must have failed to achieve symptom control after previous treatment with a preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz].</p>
Age Restriction	<p>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.</p>
Prescriber Restriction	Licensed Practitioner

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

Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## COSENTYX UNOREADY PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderate to severe chronic plaque psoriasis: The member has a diagnosis of moderate to severe plaque psoriasis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, preferred ustekinumab product (i.e., Stelara, Orlum, Yesintek), or Tremfya. Psoriatic Arthritis: The member has a diagnosis of active psoriatic arthritis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, Skyrizi, Rinvoq, preferred ustekinumab product (i.e., Stelara, Orlum, Yesintek), or Tremfya. Active ankylosing spondylitis: The member has a diagnosis of active ankylosing spondylitis AND The member must have failed to achieve symptom control after previous treatment with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq. 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 two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz] and Rinvoq. 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 AND The member must have failed to achieve symptom control after previous treatment with a preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz].</p>
Age Restriction	<p>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.</p>
Prescriber Restriction	Licensed Practitioner

## COSENTYX UNOREADY PEN - PEN INJECTOR (ML)

Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## COTELIC - 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 (binimatinib). 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., Braftovi (encorafenib) with Mektovi (binimatinib) 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## CRESEMBA - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Familial short QT syndrome.
Required Medical Information	Invasive Aspergillosis and Invasive Mucormycosis: Member must have diagnosis of invasive aspergillosis or invasive mucormycosis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## DANZITEN - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on any nilotinib (e.g. Tasigna, Danzitien).
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	

## 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 imatinib or sunitinib or Stivarga (regorafenib). [Pediatric] Chronic Myelogenous Leukemia (CML): The member has a diagnosis of chronic myeloid leukemia (CML) that is Philadelphia 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	

## DAURISMO - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
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.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## deferasirox - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Platelet counts less than 50,000/mcL. (Per FDA label, Deferasirox is contraindicated in patients with platelets below 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 3 mg/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	

## 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	

## **diclofenac sodium - DROPS**

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PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Osteoarthritis. Member has a diagnosis of osteoarthritis of the knee(s).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## **diclofenac sodium - GEL (GRAM)**

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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	

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

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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	

## 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	

## 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	

## 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	

## DUPIXENT PEN - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Atopic Dermatitis: The member has a diagnosis of moderate to severe Atopic Dermatitis (e.g. erythema, 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/ointment, triamcinolone acetonide 0.5%) OR one topical calcineurin inhibitor (e.g. pimecrolimus cream or tacrolimus).</p> <p>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).</p> <p>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.</p>
Age Restriction	<p>Atopic dermatitis: The member must be 6 months of age or older.</p> <p>Chronic rhinosinusitis with nasal polyposis and Chronic Spontaneous Urticaria: The member must be 12 years of age or older.</p> <p>Prurigo Nodularis, Bullous Pemphigoid, and COPD with an eosinophilic phenotype: The member must be 18 years of age or older.</p> <p>Eosinophilic Esophagitis: 1 year of age or older.</p>
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## DUPIXENT PEN - PEN INJECTOR (ML)

Other Criteria	<p>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 AND prescribed by or in consultation with a dermatologist, allergist, or immunologist. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype: The member has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) AND The member has an eosinophilic phenotype defined 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 beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) OR LABA-LAMA therapy if inhaled corticosteroids are contraindicated. Bullous Pemphigoid: The member has a diagnosis of bullous pemphigoid confirmed by biopsy or serologic tests AND Prescribed by or in consultation with a dermatologist, allergist, or immunologist AND member has had previous treatment with, intolerance or contraindication to one high potency topical corticosteroid (e.g. augmented betamethasone dipropionate 0.05%, clobetasol cream/ointment 0.05%, triamcinolone acetonide 0.5%) OR oral corticosteroid (e.g. prednisone).</p>
Part B Prerequisite	

## DUPIXENT SYRINGE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Atopic Dermatitis: The member has a diagnosis of moderate to severe Atopic Dermatitis (e.g. erythema, 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/ointment, triamcinolone acetonide 0.5%) OR one topical calcineurin inhibitor (e.g. pimecrolimus cream or tacrolimus).</p> <p>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).</p> <p>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.</p>
Age Restriction	<p>Atopic dermatitis: The member must be 6 months of age or older.</p> <p>Chronic rhinosinusitis with nasal polyposis and Chronic Spontaneous Urticaria: The member must be 12 years of age or older.</p> <p>Prurigo Nodularis, Bullous Pemphigoid, and COPD with an eosinophilic phenotype: The member must be 18 years of age or older.</p> <p>Eosinophilic Esophagitis: 1 year of age or older.</p>
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## DUPIXENT SYRINGE - SYRINGE (ML)

Other Criteria	<p>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 AND prescribed by or in consultation with a dermatologist, allergist, or immunologist. Chronic Obstructive Pulmonary Disease (COPD) with an eosinophilic phenotype: The member has a diagnosis of Chronic Obstructive Pulmonary Disease (COPD) AND The member has an eosinophilic phenotype defined 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 beta agonist (LABA) and long-acting muscarinic antagonist (LAMA) OR LABA-LAMA therapy if inhaled corticosteroids are contraindicated. Bullous Pemphigoid: The member has a diagnosis of bullous pemphigoid confirmed by biopsy or serologic tests AND Prescribed by or in consultation with a dermatologist, allergist, or immunologist AND member has had previous treatment with, intolerance or contraindication to one high potency topical corticosteroid (e.g. augmented betamethasone dipropionate 0.05%, clobetasol cream/ointment 0.05%, triamcinolone acetonide 0.5%) OR oral corticosteroid (e.g. prednisone).</p>
Part B Prerequisite	

## 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	

## ELIGARD - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
Required Medical Information	The patient must have 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	

## ELIGARD (3 MONTH) - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
Required Medical Information	The patient must have 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	

## ELIGARD (4 MONTH) - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
Required Medical Information	The patient must have 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	

## ELIGARD (6 MONTH) - SYRINGE (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
Required Medical Information	The patient must have 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	

## 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	

## 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	

## 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	

## 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	

## ENBREL - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). 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.</p> <p>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). Psoriatic Arthritis: Diagnosis of 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.</p> <p>Juvenile Psoriatic Arthritis: Diagnosis of active juvenile psoriatic arthritis (JPsA). Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide).</p>
Age Restriction	Must be 18 years of age for Ankylosing Spondylitis, Psoriatic arthritis, or RA. Must be 4 years of age for Plaque Psoriasis. Must be 2 years of age for Polyarticular Juvenile Idiopathic Arthritis and Juvenile Psoriatic Arthritis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## ENBREL MINI - CARTRIDGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). 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.</p> <p>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). Psoriatic Arthritis: Diagnosis of 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.</p> <p>Juvenile Psoriatic Arthritis: Diagnosis of active juvenile psoriatic arthritis (JPsA). Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide).</p>
Age Restriction	Must be 18 years of age for Ankylosing Spondylitis, Psoriatic arthritis, or RA. Must be 4 years of age for Plaque Psoriasis. Must be 2 years of age for Polyarticular Juvenile Idiopathic Arthritis and Juvenile Psoriatic Arthritis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## ENBREL SURECLICK - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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). 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.</p> <p>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). Psoriatic Arthritis: Diagnosis of 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.</p> <p>Juvenile Psoriatic Arthritis: Diagnosis of active juvenile psoriatic arthritis (JPsA). Member has had prior therapy, contraindication, or intolerance with a DMARD (e.g. methotrexate, cyclosporine, leflunomide).</p>
Age Restriction	Must be 18 years of age for Ankylosing Spondylitis, Psoriatic arthritis, or RA. Must be 4 years of age for Plaque Psoriasis. Must be 2 years of age for Polyarticular Juvenile Idiopathic Arthritis and Juvenile Psoriatic Arthritis.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## ENSACOVE - CAPSULE

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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

## 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	

## 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	

## 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	

## EPRONTIA - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 one of the following: a serotonin and norepinephrine reuptake inhibitor or a tricyclic antidepressant.</p> <p>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.</p> <p>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.</p>
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	

## 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	

## 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]). 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 LHRH analog [i.e., LHRH agonist/ antagonist]).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 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.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	

## 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	

## EULEXIN - CAPSULE

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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	

## 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). 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 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 suspension is being used as adjunctive therapy.
Part B 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	

## EXXUA - TABLET, EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Prolonged QTc interval greater than 450 msec at baseline. Congenital long QT syndrome. Severe hepatic impairment.
Required Medical Information	Major Depressive Disorder: The member must be utilizing Exxua (gepirone) for the treatment of major depressive disorder (MDD) AND The member has had prior therapy, contraindication, or intolerance to any two antidepressants from any of the following categories: generic SSRI (e.g., citalopram, fluoxetine, paroxetine, or sertraline), generic SNRI (e.g., venlafaxine or duloxetine), bupropion OR mirtazapine.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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, olanzapine, quetiapine, ziprasidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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, olanzapine, quetiapine, ziprasidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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, olanzapine, quetiapine, ziprasidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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, olanzapine, quetiapine, ziprasidone, or aripiprazole.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## felbamate - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Partial-Onset (Focal) Seizures: Member has a diagnosis of partial-onset (focal) seizures AND The provider attests that the members epilepsy is so severe that the risk of aplastic anemia is deemed acceptable in light of the benefits conferred by its use AND Member has normal baseline serum transaminases (AST/ALT) AND Felbamate (Felbate) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) 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).</p> <p>Lennox-Gastaut Syndrome: The member has a diagnosis of seizures associated with Lennox-Gastaut syndrome AND Felbamate (Felbate) is prescribed by or in consultation with a specialist (i.e. neurologist, epileptologist) AND The provider attests that the member's epilepsy is so severe that the risk of aplastic anemia is deemed acceptable in light of the benefits conferred by its use AND Member has normal baseline serum transaminases (AST/ALT) 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).</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## fingolimod - CAPSULE

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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	

## 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	

## FIRMAGON - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
Required Medical Information	The patient 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	

## FIRMAGON KIT W DILUENT SYRINGE - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
Required Medical Information	The patient 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	

## FORTEO - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Osteoporosis in Postmenopausal Women: The member must have a diagnosis of osteoporosis AND the member must be postmenopausal AND The member must meet one of the following criteria: The member must be at a high risk of fracture defined as a history of osteoporotic fracture or The member has multiple risk factors for fracture (e.g. inflammatory joint disorders, diabetes, hyperthyroidism, liver disease) OR The member has failed or is intolerant to at least ONE other available osteoporosis therapy (e.g. bisphosphates, RANK-ligand inhibitor, parathyroid hormone analog, sclerostin inhibitor, etc.) OR The member must be at VERY HIGH RISK for fracture as defined as: recent fracture (e.g. within the past 12 months) OR fracture while on approved therapy for treatment of osteoporosis OR fracture while on drugs causing skeletal harm (e.g. systemic corticosteroids) OR experienced multiple fractures OR has a very low T-score (e.g. less than -3.0) OR is at high risk for falls or has a history of falls OR has a very high fracture probability per FRAX (e.g. greater than 30% major osteoporotic fracture, greater than 4.5% hip fracture). Glucocorticoid-Induced Osteoporosis: The member is taking sustained systemic glucocorticoid therapy (daily dosage equivalent to 5 mg or greater of prednisone). Hypogonadal Osteoporosis: The member has a diagnosis of primary or hypogonadal osteoporosis AND The member is at high risk of fracture as defined as: a history of osteoporotic fracture OR multiple risk factors for 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).</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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	

## GAMUNEX-C - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 hypogammaglobinemic (IgG less than 400mg/dL). Hematopoietic Stem Cell Transplantation (HSCT). Is within first 100 days of allogenic hematopoietic 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).</p>
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	<p>Infections in Low-Birthweight Neonates. Prophylaxis and treatment of infections in high-risk preterm low-birth weight members. Diagnosed staphylococcal/streptococcal toxic shock syndrome. Infection is refractory to several hours of aggressive therapy, undrainable focus is present or has persistent oliguria with pulmonary edema. Diagnosed autoimmune neutropenia and G-CSF therapy not appropriate.</p> <p>Autoimmune Hemolytic Anemia. Refractory to corticosteroid therapy and splenectomy, or those whom corticosteroid therapy and splenectomy is contraindicated. Myasthenia Gravis. Experiencing acute myasthenic crisis with decompensation. Has tried or cannot use at least 1 other treatment (e.g., corticosteroids, azathioprine, cyclosporine, cyclophosphamide). Guillain-Barre Syndrome. Severely affected by the disease and requires aid to walk. Diagnosed with biopsy-proven polymyositis OR dermatomyositis and has failed treatment with corticosteroids and azathioprine or methotrexate. Diagnosed multifocal motor neuropathy confirmed by electrophysiologic studies. Diagnosed relapsing-remitting multiple sclerosis and has tried or cannot use at least one 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. 1 of the following criteria are met: Electrodiagnostic evidence of demyelinating neuropathy in at least two limbs OR Muscle weakness and diagnostic testing was conducted in accordance with AAN diagnostic criteria. Diagnosis of Lambert-Eaton myasthenic syndrome confirmed by electrophysiologic studies. Has tried or cannot use at least 1 of the following: diaminopyridine, azathioprine, corticosteroids, or anticholinesterases. Neonate diagnosed with isoimmune hemolytic disease. Allosensitized Solid Organ Transplantation. Allosensitized members who are awaiting solid organ transplant. Multiple Myeloma. Has life-threatening infections OR member is experiencing hypogammaglobulinemia (IgG less than or equal to 400mg/dL).</p> <p>Autoimmune Blistering Diseases. Biopsy-proven diagnosis of an autoimmune blistering disease such as epidermolysis bullosa acquisista, etc. Has tried or cannot use at least 1 conventional therapy or has rapidly progressive disease in which clinical response could not be affected quickly enough using conventional agents. Stiff-Person Syndrome. Has tried or cannot use at least 1 other intervention (e.g. diazepam). Systemic Lupus Erythematosus. Active/chronic SLE that is refractory to corticosteroid therapy or members with hemolytic anemia/ thrombocytopenia. Prevention of Bacterial / Viral Infections in Non-primary 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.</p>
Part B Prerequisite	

## 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	

## 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	

## GILOTRIF - 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 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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Six month duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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 metastatic 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	

## glutamine (sickle cell) - POWDER IN PACKET (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Sickle Cell Disease: The member has a diagnosis of sickle cell disease AND has experienced at least 2 or more sickle cell crises (i.e., medical facility visit for sickle cell related pain, acute chest syndrome, priapism, or hepatic/splenic sequestration) in the previous 12 months AND Has had previous treatment, intolerance, or contraindication with hydroxyurea capsule.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## HAEGARDA - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Hereditary Angioedema (HAE) Type 1 and 2 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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## HAEGARDA - VIAL (EA)

Other Criteria	Hereditary Angioedema with normal C1-INH (HAE Type 3) Prophylaxis: The member must have a diagnosis of hereditary angioedema with normal C1-INH (HAE-nl-C1INH) or type 3. The member must have documented labs showing normal C4 level AND normal C1-INH antigen level AND normal C1-INH functional (%) level. 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 AND The member has episodic angioedema affecting characteristic organs (without urticaria/hives). The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). The member has one of the following: A family history of recurrent angioedema OR Documented labs showing the presence of a mutation associated with HAE-normal-C1INH [i.e. HAE-FXII, HAE-PLG (plasminogen), HAE-ANGPT1 (angiopoeitin-1), and HAE-KNG1 (kininogen-1)]. 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. The member must be using Haegarda for prophylaxis to prevent attacks of HAE.
Part B Prerequisite	

## HERNEXEOS - 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 unresectable or metastatic, non-squamous, non-small cell lung cancer AND The disease is documented positive for HER2 (ERBB2) tyrosine kinase domain activating mutations AND The member has received prior systemic therapy (e.g., platinum-based chemotherapy) AND Hernexeos (zongertinib) will be given as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## HYRNUO - TABLET

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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

## IBRANCE - CAPSULE

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 Fulvestrant: 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 (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 Itovobe (inavolisib) and fulvestrant.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	

## IBTROZI - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	ROS1 Positive NSCLC: The member has diagnosis of locally advanced or metastatic non-small cell lung cancer (NSCLC) AND The member has disease which is ROS-1 rearrangement(s) positive AND The member will be using Ibtrozi (taletrectinib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## icatibant - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Hereditary Angioedema (HAE) Type 1 and 2: 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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## icatibant - SYRINGE (ML)

Other Criteria	Hereditary Angioedema with normal C1-INH (HAE Type 3): The member must have a diagnosis of hereditary angioedema with normal C1-INH (HAE-nl-C1INH) or type 3. The member must have documented labs showing normal C4 level AND normal C1-INH antigen level AND normal C1-INH functional (%) level. 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 AND The member has episodic angioedema affecting characteristic organs (without urticaria/hives). The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). The member has one of the following: A family history of recurrent angioedema OR Documented labs showing the presence of a mutation associated with HAE-normal-C1INH [i.e. HAE-FXII, HAE-PLG (plasminogen), HAE-ANGPT1 (angiopoietin-1), and HAE-KNG1 (kininogen-1)]. 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. The member is using icatibant for treatment of acute attacks of HAE.
Part B Prerequisite	

## 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	

## 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	

## 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 Kit (CD117)-positive GIST. The member has a diagnosis of Dermatofibrosarcoma 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 must not harbor the D816v mutation of C-kit. Melanoma. 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 Leukemia (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 Leukemia (ALL). The member is newly diagnosed with Ph+ ALL AND the member will be using imatinib in combination with chemotherapy.
Part B Prerequisite	

## 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	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: 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	cGVHD: Member age is 1 year or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 Kit (CD117)-positive GIST. The member has a diagnosis of Dermatofibrosarcoma 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 myelomonocytic leukemia, atypical chronic myeloid leukemia, juvenile myelomonocytic leukemia).The member has a diagnosis of aggressive systemic mastocytosis. The member must not harbor the D816V mutation of C-kit. Melanoma. 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 Leukemia (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 Leukemia (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

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Part B Prerequisite	
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## 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	

## INLURIYO - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Estrogen Receptor (ER) Positive Breast Cancer: The member has a diagnosis of ER-positive, HER2-negative advanced or metastatic breast cancer AND The breast cancer has a documented ESR1-mutation AND The member has experienced progressive disease following at least one prior line of endocrine therapy (e.g., aromatase inhibitor, CDK 4/6 inhibitor).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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, oncocytic 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	

## INQOVI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## INREBIC - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Inrebic (federatinib).
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 (federatinib) 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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	

## 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 relapsed 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	

## 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. 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	

## JYNARQUE - TABLET, SEQUENTIAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Autosomal Dominant Polycystic Kidney Disease. Has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) AND Must be at risk of rapidly progressive disease (e.g. advanced stage kidney disease according to age, hypertension before age 35, enlarged kidneys) AND Must have CKD stage 2 - 4 AND Medication is being used to slow kidney function decline.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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). Heart Failure: The member has a diagnosis of heart failure AND has a left ventricular ejection fraction greater than or equal to 40%.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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 immunosupresant therapy with cyclosporine.
Age Restriction	NA
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	NA
Part B Prerequisite	

## 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	

## 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	

## 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	

## 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	

## 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	

## 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	

## lenalidomide - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on lenalidomide.
Required Medical Information	<p>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.</p> <p>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.</p> <p>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).</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	<p>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.</p> <p>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.</p>
Part B Prerequisite	

## LENVIMA - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Lenvima (lenvatinib).
Required Medical Information	<p>Thyroid Cancer: The member has a diagnosis of locally recurrent or metastatic, progressive differentiated thyroid cancer (i.e. papillary carcinoma, follicular carcinoma or oncocytic carcinoma) AND The tumors are not responsive to radio-iodine treatment AND Lenvima (lenvatinib) will be used as monotherapy.</p> <p>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].</p> <p>Hepatocellular Carcinoma: The member has a diagnosis of unresectable carcinoma AND Lenvima (lenvatinib) will be given as a single agent as first line therapy.</p> <p>Endometrial cancer: The member has a diagnosis of metastatic or recurrent 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 is not a candidate for curative surgery or radiation AND The member has experienced disease progression on prior or following systemic therapy in any setting AND Lenvima (lenvatinib) will be given in combination with Keytruda (pembrolizumab) as subsequent therapy.</p> <p>Renal cell carcinoma- first line therapy: The member has a diagnosis of advanced renal cell carcinoma AND Lenvima (lenvatinib) will be given in combination with Keytruda (pembrolizumab) as first line therapy.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
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 leiomyoma. 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	

## 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	

## **Iomustine - CAPSULE**

PA Criteria	Criteria Details
<b>Off-Label Uses</b>	
<b>Exclusion Criteria</b>	The member has experienced disease progression while on Gleostine (Iomustine).
<b>Required Medical Information</b>	Brain Tumors. The member has a diagnosis of primary or metastatic brain tumor AND one of the following applies: the member will use Gleostine (Iomustine) 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 (Iomustine) as a component of combination chemotherapy.
<b>Age Restriction</b>	
<b>Prescriber Restriction</b>	Licensed Practitioner
<b>Coverage Duration</b>	Plan Year Duration
<b>Other Criteria</b>	
<b>Part B Prerequisite</b>	

## 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	

## LORBRENA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## LUMAKRAS - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has experienced disease progression on a KRAS G12C inhibitor (e.g., sotorasib, adagrasib). [All indications]
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 as subsequent treatment. 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	

## LUPRON DEPOT - SYRINGE KIT (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
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 leiomyoma. 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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
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 leiomyoma. 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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs.
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 leiomyoma. 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	

## 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	

## 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. 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 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]) 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.
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	

## MEKINIST - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	<p>Melanoma - Unresectable or metastatic: Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimatinib). 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 Braftovi (encorafenib) with Mektovi (binimatinib)]. 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 (binimatinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)]. Adjuvant melanoma: member is taking Mekinist (trametinib) total treatment for more than one year. Members on concomitant Yervoy (ipilimumab), Zelboraf (vemurafenib), Opdivo (nivolumab), Keytruda (pembrolizumab), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimatinib). Members that have experienced disease progression while on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)]. 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 Braftovi (encorafenib) with Mektovi (binimatinib)].</p>

## MEKINIST - TABLET

Required Medical Information	<p>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).</p> <p>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 has a documented BRAF V600 activating mutation AND The member will be using Mekinist (trametinib) in combination with Tafinlar (dabrafenib) for adjuvant treatment.</p> <p>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).</p> <p>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.</p> <p>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).</p>
Age Restriction	Low-grade Glioma only: The member is a pediatric age 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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). 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 (binimatinib). 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 (binimatinib).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## memantine - TABLET

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	

## 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	

## MODEYSO - CAPSULE

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PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Diffuse Midline Glioma: The member has a diagnosis of diffuse midline glioma AND The disease has documented H3 K27M mutation AND The member has experienced disease progression or recurrence following prior therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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: 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. 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	Plan year duration
Other Criteria	
Part B Prerequisite	

## NEXLETOL - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Primary Hyperlipidemia: Diagnosis of primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) and one of the following: used as adjunctive therapy after failure to achieve goal LDL-C reduction on recommended statin therapy (e.g., atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin) OR statin intolerant (e.g., has symptoms of rhabdomyolysis, statin-associated muscle symptoms) Cardiovascular Disease: diagnosis of: established cardiovascular disease (CVD) OR member is at high risk for a CVD event but without established CVD and one of the following: used as adjunctive therapy after failure to achieve goal LDL-C reduction on recommended statin therapy (e.g., atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin) OR unable to take recommended statin therapy due to statin intolerance (e.g., has symptoms of rhabdomyolysis, statin-associated muscle symptoms) and including those not taking a statin.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## NEXLIZET - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Primary Hyperlipidemia: Diagnosis of primary hyperlipidemia (including heterozygous familial hypercholesterolemia [HeFH]) and one of the following: used as adjunctive therapy after failure to achieve goal LDL-C reduction on recommended statin therapy (e.g., atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin) OR statin intolerant (e.g., has symptoms of rhabdomyolysis, statin-associated muscle symptoms)</p> <p>Cardiovascular Disease: diagnosis of: established cardiovascular disease (CVD) OR member is at high risk for a CVD event but without established CVD and one of the following: used as adjunctive therapy after failure to achieve goal LDL-C reduction on recommended statin therapy (e.g., atorvastatin, rosuvastatin, simvastatin, pravastatin, lovastatin) OR unable to take recommended statin therapy due to statin intolerance (e.g., has symptoms of rhabdomyolysis, statin-associated muscle symptoms) and including those not taking a statin.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## nilotinib d-tartrate - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression on any nilotinib (e.g. Tasigna, Danzitén).
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	

## nilotinib hcl - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on any nilotinib product. 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 member 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 imatinib, 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	

## 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 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	

## NIVESTYM - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Neutropenia in Myelodysplastic Syndromes: The member must have a diagnosis of neutropenia associated with myelodysplastic syndrome.</p> <p>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.</p> <p>Febrile Neutropenia Prophylaxis: The member must have a diagnosis of non-myeloid malignancy (e.g., solid tumors) AND The member must also meet ONE OR MORE of the following criteria (NOTE: the chemotherapy regimens risk of febrile neutropenia should be assessed per current ASCO and NCCN guidelines for myeloid growth factors): Current chemotherapy regimen has a risk of febrile neutropenia of greater than 20% OR Current chemotherapy regimen has a risk of febrile neutropenia of 10 to 20%, and member has at least ONE of the following risk factors OR Current chemotherapy regimen has a risk of febrile neutropenia of less than 10% and member has at least TWO of the following risk factors:</p> <p>Risk Factors:</p> <p>Prior chemotherapy or radiation therapy, Persistent neutropenia, Bone marrow involvement by tumor, Recent surgery and/or open wounds, Liver dysfunction (bilirubin greater than 2 mg/dL), Renal dysfunction (creatinine clearance less than 50 mL/min), Age greater than 65 receiving full chemotherapy dose intensity OR Member experienced previous neutropenic fever complication or dosing limiting neutropenic event on a prior cycle of similar chemotherapy OR The member is receiving a dose-dense chemotherapy regimen OR Member is using as secondary prophylaxis in the curative setting to maintain dosing schedule and/or intensity.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Months Duration

## NIVESTYM - 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 is using as a component of a hematopoietic stem cell mobilization protocol and one of the following applies: is scheduled for autologous peripheral-blood stem cell (PBSC) transplantation, is storing cells for a possible future autologous transplant, or is 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	

## 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]). 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) alone or with docetaxel AND the member will use Nubeqa (darolutamide) in combination with androgen deprivation therapy (e.g. previous bilateral orchiectomy or LHRH analog [i.e., LHRH agonist/ antagonist]).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## octreotide acetate - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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.</p> <p>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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## octreotide,microspheres - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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.</p> <p>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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## OGSIVEO - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Member has had disease progression on Ogsiveo (nirogacestat).
Required Medical Information	Pending CMS Review
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## OJJAARA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Ojaara (momelotinib).
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 has anemia* AND The member will be using Ojaara (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.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## OMNITROPE - CARTRIDGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 test 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/m<sup>2</sup> OR Less than or equal to 3 mcg/L in patients with a BMI of 25 - 30 kg/m<sup>2</sup> and high pre-test probability, Less than or equal to 1 mcg/L in patients with a BMI of 25 - 30 kg/m<sup>2</sup> 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/m<sup>2</sup>. 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.</p>
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.
Part B Prerequisite	

## ONUREG - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 at least two of the following generic atypical antipsychotics: risperidone, olanzapine, quetiapine, ziprasidone, aripiprazole, 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 Oripiprazole 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.
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	

## ORGOVYX - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concomitant use with other luteinizing hormone-releasing hormone (LHRH) analogs. 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	

## 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	

## OTULFI - 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 treatments (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 Crohn's disease. Moderate to severely 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 Crohn's Disease and Ulcerative Colitis: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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, oncocytic 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 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	

## PEGASYS - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 both of the following: tenofovir disoproxil fumarate and entecavir.</p> <p>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 elevations in serum alanine aminotransferase (ALT) AND the member must have had prior therapy, contraindication, or intolerance with both of the following: tenofovir disoproxil fumarate and entecavir.</p> <p>Chronic Hepatitis C - Adults: The member must have a diagnosis of chronic hepatitis C AND The member has compensated liver disease AND Pegasys (peginterferon alpha-2a) will be taken in combination with at least 1 other medication indicated for the treatment of chronic Hepatitis C AND the member has had previous treatment, contraindication, or intolerance to Epclusa.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 to 48 week treatment course depending on the disease state and/or genotype.
Other Criteria	<p>Chronic Hepatitis C - Pediatrics: The member must have a diagnosis of chronic hepatitis C 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.</p>
Part B Prerequisite	

## 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	

## 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	

## 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	

## 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	

## pirfenidone - TABLET

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	

## 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, carfilzomib) 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 bortezomib, with dexamethasone and carfilzomib, 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	

## posaconazole - TABLET, DELAYED RELEASE (ENTERIC COATED)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 and fluconazole.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## PREVYMIS - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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-seronegative (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).</p>
Age Restriction	<p>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.</p> <p>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.</p>
Prescriber Restriction	Licensed Practitioner
Coverage Duration	12 Months Duration
Other Criteria	
Part B Prerequisite	

## PROMACTA - POWDER IN PACKET (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	ITP members with previous documented failure of eltrombopag.
Required Medical Information	<p>Persistent or Chronic Immune Thrombocytopenic Purpura. Initial Approval: The member has a diagnosis of persistent or chronic immune thrombocytopenic purpura (minimum 3-month disease history) AND The member has a platelet count of less than 50 x 10<sup>9</sup>/L. The member has had documented failure, intolerance, or contraindication to at least one course of prednisone or dexamethasone OR The member has had a splenectomy. Reauthorizations. The member has a platelet count of less than 400 x 10<sup>9</sup>/L.</p> <p>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 10<sup>9</sup>/L.</p> <p>One of the following applies: Is attempting to initiate and maintain interferon based therapy OR is currently receiving interferon based therapy. Reauthorization: The member has a platelet count of less than 400 x 10<sup>9</sup>/L AND The member continues to receive interferon based therapy.</p> <p>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 10<sup>9</sup>/L.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	

## QINLOCK - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 months duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## REPATHA PUSHTRONEX - WEARABLE INJECTOR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hypercholesterolemia: Diagnosis of hypercholesterolemia (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) defined by any of the following: Statin associated rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite 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	Hypercholesterolemia: Member must be 10 years of age or older. Cardiovascular Event Prevention: Member must be 18 years of age or older. Homozygous familial hypercholesterolemia: Member must be 10 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Cardiovascular Event Prevention: The member must have an increased risk of major adverse cardiovascular events (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) defined by any of the following: Statin associated rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMs despite 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 HoFH AND 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.

# REPATHA PUSHTRONEX - WEARABLE INJECTOR

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Part B Prerequisite	
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## REPATHA SURECLICK - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hypercholesterolemia: Diagnosis of hypercholesterolemia (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) defined by any of the following: Statin associated rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite 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	Hypercholesterolemia: Member must be 10 years of age or older. Cardiovascular Event Prevention: Member must be 18 years of age or older. Homozygous familial hypercholesterolemia: Member must be 10 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Cardiovascular Event Prevention: The member must have an increased risk of major adverse cardiovascular events (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) defined by any of the following: Statin associated rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMs despite 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 HoFH AND 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.

## REPATHA SURECLICK - PEN INJECTOR (ML)

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Part B Prerequisite	
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## REPATHA SYRINGE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Hypercholesterolemia: Diagnosis of hypercholesterolemia (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) defined by any of the following: Statin associated rhabdomyolysis OR Member has failed to achieve goal LDL-C reduction because of SAMs despite 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	Hypercholesterolemia: Member must be 10 years of age or older. Cardiovascular Event Prevention: Member must be 18 years of age or older. Homozygous familial hypercholesterolemia: Member must be 10 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	Cardiovascular Event Prevention: The member must have an increased risk of major adverse cardiovascular events (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) defined by any of the following: Statin associated rhabdomyolysis OR member has failed to achieve goal LDL-C reduction because of SAMs despite 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 HoFH AND 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.

## REPATHA SYRINGE - SYRINGE (ML)

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Part B Prerequisite	
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## RETACRIT - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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.</p> <p>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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Initial: Plan year duration. Reauth: Plan year duration.

## RETACRIT - VIAL (ML)

Other Criteria	<p>Anemia in Surgery Members: Must be scheduled to undergo elective, noncardiac, nonvascular surgery. Must have Hgb 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).</p>
Part B Prerequisite	

## RETEVMO - CAPSULE

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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	

## REVCORI - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Adenosine deaminase severe combined immune deficiency (ADA-SCID): The member has a diagnosis of adenosine deaminase severe combined immune deficiency.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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 (brexpiprazole) must be used as adjunctive (add-on) 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 therapy. 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 an as needed (prn) treatment for agitation.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## REZDIFFRA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)]: Member has a diagnosis of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH) [formerly known as nonalcoholic steatohepatitis (NASH)] confirmed by at least one of the following: Liver biopsy, Vibration-Controlled transient elastography (VCTE), or Magnetic resonance elastography (MRE) AND Member has moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) AND Provider attests member will use Rezdiffra in combination with diet and exercise AND Prescribed by or in consultation with a specialist with experience treating MASH/NASH (e.g., hepatologist, gastroenterologist) AND Member has at least one metabolic risk factors (e.g., hypertriglyceridemia, raised fasting plasma glucose, central obesity).
Age Restriction	The member is at least 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## RINVOQ - TABLET, EXTENDED RELEASE 24 HR

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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, Enbrel). 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, Enbrel). 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-adbm, adalimumab-adaz) or at least one approved systemic therapy if a TNF blocker cannot be used.</p> <p>Ankylosing Spondylitis: the member has a diagnosis of active ankylosing spondylitis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adbm, adalimumab-adaz, Enbrel). 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-adbm, adalimumab-adaz, Enbrel).</p> <p>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-adbm, adalimumab-adaz) or at least one approved systemic therapy if a TNF blocker cannot be used.</p>
Age Restriction	<p>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.</p>
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 arthritis AND the member has had prior therapy, contraindication or intolerance with one or more TNF blockers (e.g. Humira, adalimumab-adbm, adalimumab-adaz, Enbrel). Giant Cell Arteritis: the member has a diagnosis of giant cell arteritis.
Part B Prerequisite	

## 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, Enbrel). 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-adbm, adalimumab-adaz, Enbrel).
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	

## 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	

## ROZLYTREK - CAPSULE

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	

## 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	Epithelial 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## rufinamide - TABLET

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	

## RYDAPT - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	AML newly diagnosed: Members that are using Rydapt(midostaurin) for post-consolidation therapy. 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## sajazir - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Hereditary Angioedema (HAE) Type 1 and 2: 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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration

## sajazir - SYRINGE (ML)

Other Criteria	Hereditary Angioedema with normal C1-INH (HAE Type 3): The member must have a diagnosis of hereditary angioedema with normal C1-INH (HAE-nl-C1INH) or type 3. The member must have documented labs showing normal C4 level AND normal C1-INH antigen level AND normal C1-INH functional (%) level. 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 AND The member has episodic angioedema affecting characteristic organs (without urticaria/hives). The member is being treated by a specialist in hereditary angioedema (i.e. allergist and/or immunologist). The member has one of the following: A family history of recurrent angioedema OR Documented labs showing the presence of a mutation associated with HAE-normal-C1INH [i.e. HAE-FXII, HAE-PLG (plasminogen), HAE-ANGPT1 (angiopoietin-1), and HAE-KNG1 (kininogen-1)]. 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. The member is using icatibant for treatment of acute attacks of HAE.
Part B Prerequisite	

## SANDOSTATIN LAR DEPOT - VIAL (EA)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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.</p> <p>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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## sapropterin - POWDER IN PACKET (EA)

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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	

## 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	

## SECUADO - PATCH, TRANSDERMAL 24 HOURS

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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	

## 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	

## 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	

## 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	

## SKYRIZI - 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. Moderately to severely active Crohns disease: member has a diagnosis of moderately to severely active Crohns disease. Moderately to severely active ulcerative 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	

## 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), Wakix (pitolisant), or Sunosi (solriamfetol).
Part B Prerequisite	

## 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).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## sorafenib - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on sorafenib. [Applicable to all indications except Gastrointestinal stromal tumor (GIST)]
Required Medical Information	Renal Cell Carcinoma: Diagnosis of advanced renal cell carcinoma (stage IV). 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 oncocytic cell carcinoma AND Tumors are not responsive to radio-iodine treatment. Gastrointestinal stromal tumor (GIST). Diagnosis of gastrointestinal stromal tumor (GIST).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 treatments (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 Crohn's disease. Moderate to severely 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 Crohn's Disease and Ulcerative Colitis: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## STIVARGA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has experienced disease progression while on Stivarga (regorafenib). [Applicable to all indications except Gastrointestinal stromal tumor (GIST)]
Required Medical Information	<p>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.</p> <p>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.</p> <p>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 therapy (e.g., sorafenib). Soft Tissue sarcoma. Diagnosis of advanced or metastatic soft tissue sarcoma (e.g., angiosarcoma, non-adipocytic sarcoma, pleomorphic rhabdomyosarcoma) AND Stivarga (regorafenib) is being given as a single agent.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	6 Month Duration
Other Criteria	
Part B Prerequisite	

## 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	

## sunitinib malate - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on sunitinib. [Applicable to all indications except Gastrointestinal stromal tumor (GIST)]. 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, oncocytic, papillary carcinoma OR The member has a diagnosis of advanced medullary carcinoma and has disease progression or has an intolerance to Caprelsa (vandetanib) or Cometriq (cabozantinib). Advanced/Metastatic Angiosarcoma. Diagnosis of diagnosis of 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	

## 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	

## 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	

## tadalafil - TABLET

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

## 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	

# TAFINLAR - TABLET FOR SUSPENSION

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	<p>Melanoma - Unresectable or metastatic: Concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimatinib). Experienced disease progression on Tafinlar (dabrafenib). Experienced disease progression on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)]. Anaplastic Thyroid Cancer, Metastatic Solid Tumors: Concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimatinib).</p> <p>Experienced disease progression on Tafinlar (dabrafenib). Experienced disease progression on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)]. NSCLC: Concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimatinib). Experienced disease progression on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)].</p> <p>Adjuvant melanoma: Taking Tafinlar (dabrafenib) total treatment for more than 1 year. Concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Zelboraf (vemurafenib), Cotellic (cobimetinib), Braftovi (encorafenib), or Mektovi (binimatinib).</p> <p>Experienced disease progression on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)]. LGG: Experienced disease progression on Tafinlar (dabrafenib). Experienced disease progression on prior anti-BRAF/MEK combination therapy [e.g. Cotellic (cobimetinib) with Zelboraf (vemurafenib) or Braftovi (encorafenib) with Mektovi (binimatinib)].</p>

## TAFINLAR - TABLET FOR SUSPENSION

Required Medical Information	<p>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 has a documented BRAF V600 activating mutation AND The member will be using Tafinlar (dabrafenib) in combination with Mekinist (trametinib) for adjuvant treatment.</p> <p>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.</p> <p>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).</p>
Age Restriction	Low-grade Glioma only: The member is a pediatric age 1 year of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]) 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	

## 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	

## 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	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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	

## 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	

## 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	

## 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	

## 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	

## 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 (ivosidenib) 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 azacitidine. Cholangiocarcinoma: The member has locally advanced or metastatic cholangiocarcinoma AND the disease has documented isocitrate dehydrogenase-1 (IDH1) mutation AND Tibsovo (ivosidenib) will be a subsequent therapy and used as monotherapy. Myelodysplastic syndromes (MDS): The member has a diagnosis of myelodysplastic syndromes AND The member has relapsed or refractory disease AND The member has a documented IDH1 mutation AND The member will be using Tibsovo (ivosidenib) as monotherapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	MDS: Plan year duration. All other indications: 6 Months Duration
Other Criteria	
Part B Prerequisite	

## topiramate - SOLUTION, ORAL

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 one of the following: a serotonin and norepinephrine reuptake inhibitor or a tricyclic antidepressant.</p> <p>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.</p> <p>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.</p>
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	

## 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	

## 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 must weigh at least 40kg 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 AND the member must weigh at least 40kg. 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	Plaque Psoriasis, Psoriatic Arthritis: The member must be 6 years of age or older. All other indications: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## TREMFYA ONE-PRESS - AUTO-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 must weigh at least 40kg 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 AND the member must weigh at least 40kg. 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	Plaque Psoriasis, Psoriatic Arthritis: The member must be 6 years of age or older. All other indications: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 must weigh at least 40kg 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 AND the member must weigh at least 40kg. 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	Plaque Psoriasis, Psoriatic Arthritis: The member must be 6 years of age or older. All other indications: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## TREMFYA PEN INDUCTION PK(2PEN) - 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 must weigh at least 40kg 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 AND the member must weigh at least 40kg. 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	Plaque Psoriasis, Psoriatic Arthritis: The member must be 6 years of age or older. All other indications: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## tretinoin - GEL (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	

## 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	

## 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/AKT1/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	

## 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 Tukysa will be given in combination with trastuzumab product.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## TYENNE - SYRINGE (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderately to Severely Active Rheumatoid Arthritis: The member must have a diagnosis of moderately to severely active rheumatoid arthritis AND The member has prior therapy, contraindication, or intolerance with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq.</p> <p>Polyarticular Juvenile Idiopathic Arthritis (PJIA): The member must have a diagnosis of active polyarticular juvenile idiopathic arthritis. The member has had prior therapy, contraindication, or intolerance with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq.</p> <p>Systemic Juvenile Idiopathic Arthritis: The member must have a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) or as formerly known, systemic juvenile rheumatoid arthritis.</p> <p>Giant Cell Arteritis: The member must have a diagnosis of giant cell arteritis AND the member has had prior therapy, contraindication, or intolerance with Rinvoq.</p>
Age Restriction	Member must be 18 years and older. For the treatment of PJIA and SJIA the member must be at least 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## TYENNE AUTOINJECTOR - PEN INJECTOR (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>Moderately to Severely Active Rheumatoid Arthritis: The member must have a diagnosis of moderately to severely active rheumatoid arthritis AND The member has prior therapy, contraindication, or intolerance with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq.</p> <p>Polyarticular Juvenile Idiopathic Arthritis (PJIA): The member must have a diagnosis of active polyarticular juvenile idiopathic arthritis. The member has had prior therapy, contraindication, or intolerance with two of the following: preferred adalimumab product [i.e., adalimumab-adbm, adalimumab-adaz], Enbrel, or Rinvoq.</p> <p>Systemic Juvenile Idiopathic Arthritis: The member must have a diagnosis of active systemic juvenile idiopathic arthritis (SJIA) or as formerly known, systemic juvenile rheumatoid arthritis.</p> <p>Giant Cell Arteritis: The member must have a diagnosis of giant cell arteritis AND the member has had prior therapy, contraindication, or intolerance with Rinvoq.</p>
Age Restriction	Member must be 18 years and older. For the treatment of PJIA and SJIA the member must be at least 2 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## UPTRAVI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH): The member must have a diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization. The member must have had prior therapy, intolerance to, or contraindication to: ONE Endothelin receptor antagonist (e.g., ambrisentan, bosentan, macitentan).
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## USTEKINUMAB - 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 treatments (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 Crohn's disease. Moderate to severely 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 Crohn's Disease and Ulcerative Colitis: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## VALCHLOR - GEL (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## VENCLEXTA - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has 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: The member has received at least one prior therapy OR The request is for first-line therapy AND the member is using Venclexta (venetoclax) as part of a supported combination therapy. Mantle Cell Lymphoma: The member has a diagnosis of MCL AND one of the following applies: the member is using Venclexta (venetoclax) as second or subsequent line therapy AND the member is using Venclexta (venetoclax) as monotherapy or in combination with a rituximab product or in combination with Imbruvica (ibrutinib) OR The member has untreated, TP53 mutated disease AND the member is using Venclexta (venetoclax) in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab). Acute Myeloid Leukemia: The member has a diagnosis of acute myeloid leukemia (AML) AND one of the following applies: the disease is newly diagnosed AND the member is 75 years or older AND the member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine OR the disease is newly diagnosed AND the 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) AND the member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine OR The member has relapsed/refractory disease AND Venclexta (venetoclax) will be used as part of supported combination therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## VENCLEXTA STARTING PACK - TABLET, DOSE PACK

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	The member has 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: The member has received at least one prior therapy OR The request is for first-line therapy AND the member is using Venclexta (venetoclax) as part of a supported combination therapy. Mantle Cell Lymphoma: The member has a diagnosis of MCL AND one of the following applies: the member is using Venclexta (venetoclax) as second or subsequent line therapy AND the member is using Venclexta (venetoclax) as monotherapy or in combination with a rituximab product or in combination with Imbruvica (ibrutinib) OR The member has untreated, TP53 mutated disease AND the member is using Venclexta (venetoclax) in combination with Brukinsa (zanubrutinib) and Gazyva (obinutuzumab). Acute Myeloid Leukemia: The member has a diagnosis of acute myeloid leukemia (AML) AND one of the following applies: the disease is newly diagnosed AND the member is 75 years or older AND the member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine OR the disease is newly diagnosed AND the 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) AND the member will be using Venclexta (venetoclax) in combination with azacitidine, or decitabine, or low-dose cytarabine OR The member has relapsed/refractory disease AND Venclexta (venetoclax) will be used as part of supported combination therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B 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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	The member must be using clozapine ODT or Versacloz (clozapine oral solution) for treatment-resistant schizophrenia. The member must have had prior therapy or intolerance to generic clozapine tablets.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## vigabatrin - 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	

## vigadron - 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	

## 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	

## 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	

## **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	

## 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	

## 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	

## 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 10 <sup>9</sup> /L.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 oligodendrolioma 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	

## 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). Member must be non-cirrhotic OR have compensated cirrhosis (Child-Pugh Class A). The member has relapsed after completing a full course of or has a contraindication to Epclusa. (Note: Previous treatment with Epclusa does not apply if member has had prior treatment failure with a full course of glecaprevir/pibrentasvir therapy).
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	

## 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 will perform a 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	

## VRAYLAR - CAPSULE

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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.</p> <p>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.</p> <p>Bipolar 1 Disorder (Bipolar Depression): The member must have a diagnosis of bipolar 1 disorder (bipolar depression) and the member must have documentation of prior treatment, intolerance, or contraindication to quetiapine or lurasidone.</p> <p>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 for MDD AND The member must have documentation of prior therapy, 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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## WELIREG - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	von Hippel Lindau (VHL) Disease and Renal Cell Carcinoma (RCC): Member experiences disease progression on Welireg (belzutifan).
Required Medical Information	<p>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. 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.</p> <p>Pheochromocytoma or Paraganglioma (PPGL): The member has locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL).</p>
Age Restriction	Pheochromocytoma or Paraganglioma (PPGL): The member is 12 years and older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## WINREVAIR - KIT

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Pulmonary Arterial Hypertension (PAH): The member must have a diagnosis of pulmonary arterial hypertension (WHO Group 1) confirmed by right heart catheterization AND Member has WHO functional class II or IV symptoms AND One of the following: Member is stable on combination therapy (e.g. PDE5i (e.g. sildenafil or tadalafil) or Adempas (riociguat) and an ERA (e.g. ambrisentan, bosentan, macitentan) OR Member is stable on PAH monotherapy (e.g. PDE5i, sGC, ERA) due to intolerance of combination therapy.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## XALKORI - PELLETS IN DISPENSING CAPSULE

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 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 OR The member has a documented MET exon 14 skipping mutation. 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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	

## 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	

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

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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	

## XDEMVY - DROPS

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PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Demodex blepharitis: Has a diagnosis of Demodex blepharitis.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## XERMELO - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Carcinoid Syndrome. The member has a diagnosis of carcinoid syndrome diarrhea inadequately controlled with somatostatin analog (SSA) therapy AND member has received 3 months of SSA therapy (i.e., octreotide acetate, Sandostatin LAR, or Somatuline Depot) at a stable dose AND Xermelo will be used concomitantly with SSA therapy. Reauthorization: Member has not experienced severe constipation or abdominal pain with Xermelo AND Xermelo continues to demonstrate clinical benefit, as evidenced by maintained reduction in the number of daily bowel movements from baseline AND Xermelo will continue to be used concomitantly with SSA therapy.
Age Restriction	The member must be 18 years or older.
Prescriber Restriction	Licensed Practitioner.
Coverage Duration	6 months duration.
Other Criteria	
Part B Prerequisite	

## XGEVA - VIAL (ML)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Concurrent use of bisphosphonate therapy (e.g., zoledronic acid).
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.. Multiple Myeloma: The member has a diagnosis of multiple myeloma. 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.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## XOLAIR - SYRINGE (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	

## 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	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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	

## XTANDI - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	Members that have experienced disease progression while on Xtandi (enzalutamide).
Required Medical Information	<p>Prostate Cancer (metastatic castration-resistant): The member has metastatic 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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]).</p> <p>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 luteinizing hormone-releasing hormone (LHRH) analog [i.e., LHRH agonist/ antagonist]).</p> <p>Prostate Cancer (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).</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## YESINTEK - 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 treatments (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 Crohn's disease. Moderate to severely 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 Crohn's Disease and Ulcerative Colitis: The member must be 18 years of age or older.
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## ZEJULA - 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	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 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	

## ZELBORAF - TABLET

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	<p>Members on concomitant Yervoy (ipilimumab), Opdivo (nivolumab), Keytruda (pembrolizumab), Tafinlar (dabrafenib), Mekinist (trametinib), Braftovi (encorafenib), or Mektovi (binimatinib). 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. Braftovi (encorafenib) with Mektovi (binimatinib) or Tafinlar (dabrafenib) with Mekinst (trametinib)].</p>
Required Medical Information	<p>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 (cobimetinib).</p> <p>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.</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## 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 reduced serum alpha-1 antitrypsin concentrations, AND an initial serum alpha 1-antitrypsin concentration of less than 57mg/dL when measured by nephelometry OR less than 80 mg/dL when measured by radial immunodiffusion. (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	

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

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	<p>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 bisphosphonate.</p> <p>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 bisphosphonate.</p> <p>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 bisphosphonate .</p> <p>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 bisphosphonate. And the member: Is symptomatic OR is at risk for complications from their disease, to induce remission, or to normalize serum alkaline phosphatase.</p> <p>Brand Reclast request only: Members must have previous treatment, contraindication, or intolerance to generic Zoledronic acid (generic Reclast).</p>
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

## ZOLINZA - CAPSULE

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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	

## 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	

## ZORYVE - CREAM (GRAM)

PA Criteria	Criteria Details
Off-Label Uses	
Exclusion Criteria	
Required Medical Information	Atopic Dermatitis: The member has a diagnosis of mild to moderate atopic dermatitis (e.g. erythema that is faint pink to pink-red mild to moderate induration/papulation) AND The member has had previous treatment, intolerance, or contraindication to one of the following topical products: triamcinolone, mometasone, betamethasone, or clobetasol cream/ointment OR The member has had previous treatment, intolerance, or contraindication to a topical calcineurin inhibitor (e.g. tacrolimus). Previous treatment with a calcineurin inhibitor is not required for children less than 2 years of age.
Age Restriction	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan year duration
Other Criteria	
Part B Prerequisite	

## 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	

## 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 The member will be receiving Zurzuvae therapy no later than one year postpartum AND The member is not pregnant at initiation of Zurzuvae therapy 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	

## 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	

## ZYKADIA - 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 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	
Prescriber Restriction	Licensed Practitioner
Coverage Duration	Plan Year Duration
Other Criteria	
Part B Prerequisite	

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

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### Products Affected

- Astagraf XL 0.5 MG; 1 MG; 5 MG; capsule,extended release
- azathioprine 100 MG; 50 MG; 75 MG; tablet
- CellCept 200 MG/ML; 250 MG; 500 MG; capsule,extended release
- CellCept Intravenous 500 MG; intravenous solution
- cyclophosphamide 25 MG; 50 MG; tablet
- cyclosporine modified 100 MG; 100 MG/ML; 25 MG; 50 MG; capsule
- Envarsus XR 0.75 MG; 1 MG; 4 MG; tablet,extended release
- Gengraf 100 MG; 100 MG/ML; 25 MG; capsule
- Imuran 50 MG; tablet
- Medrol 16 MG; 2 MG; 4 MG; 8 MG; tablet
- methylprednisolone 16 MG; 32 MG; 4 MG; 8 MG; tablet
- mycophenolate 500 MG; intravenous solution
- mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; oral powder for suspension
- mycophenolate sodium 180 MG; 360 MG; tablet,delayed release
- Myhibbin 200 MG/ML; oral suspension
- Neoral 100 MG; 100 MG/ML; 25 MG; oral solution
- Pediapred 5 mg base/5 mL (6.7 MG/5 mL); oral solution
- Azasan 100 MG; 75 MG; tablet
- CellCept 200 MG/ML; 250 MG; 500 MG; capsule
- CellCept 200 MG/ML; 250 MG; 500 MG; tablet
- cyclophosphamide 25 MG; 50 MG; capsule
- cyclosporine 100 MG; 25 MG; capsule
- cyclosporine modified 100 MG; 100 MG/ML; 25 MG; 50 MG; oral solution
- everolimus (immunosuppressive) 0.25 MG; 0.5 MG; 0.75 MG; 1 MG; tablet
- Gengraf 100 MG; 100 MG/ML; 25 MG; oral solution
- Jylamvo 2 MG/ML; oral solution
- methotrexate sodium 2.5 MG; tablet
- Millipred 5 MG; tablet
- mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; capsule
- mycophenolate mofetil 200 MG/ML; 250 MG; 500 MG; tablet
- Myfortic 180 MG; 360 MG; tablet,delayed release
- Neoral 100 MG; 100 MG/ML; 25 MG; capsule
- Orapred ODT 10 MG; 15 MG; 30 MG; disintegrating tablet
- prednisolone 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); disintegrating tablet

- prednisolone 15 MG/5 ML; 5 MG; oral solution
- 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
- prednisone 1 MG; 10 MG; 2 MG; 2.5 MG; 20 MG; 5 MG; 5 MG/5 ML; 50 MG; oral solution
- prednisone 1 MG; 10 MG; 2 MG; 2.5 MG; 20 MG; 5 MG; 5 MG/5 ML; 50 MG; tablet,delayed release
- Prograf 0.2 MG; 0.5 MG; 1 MG; 5 MG; capsule
- Rapamune 0.5 MG; 1 MG; 1 MG/ML; 2 MG; oral solution
- Rayos 1 MG; 2 MG; 5 MG; tablet,delayed release
- Sandimmune 100 MG; 100 MG/ML; 25 MG; oral solution
- sirolimus 0.5 MG; 1 MG; 1 MG/ML; 2 MG; tablet
- tacrolimus XL 0.5 MG; 1 MG; 5 MG; capsule,extended release 24 hr
- Veripred 20 20 mg/5 mL (4 MG/ML); oral solution
- Zortress 0.25 MG; 0.5 MG; 0.75 MG; 1 MG; 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 solution
- prednisone 1 MG; 10 MG; 2 MG; 2.5 MG; 20 MG; 5 MG; 5 MG/5 ML; 50 MG; tablet
- Prednisone Intensol 5 MG/ML; oral concentrate
- Prograf 0.2 MG; 0.5 MG; 1 MG; 5 MG; oral granules in packet
- Rapamune 0.5 MG; 1 MG; 1 MG/ML; 2 MG; tablet
- Sandimmune 100 MG; 100 MG/ML; 25 MG; capsule
- sirolimus 0.5 MG; 1 MG; 1 MG/ML; 2 MG; oral solution
- tacrolimus 0.5 MG; 1 MG; 5 MG; capsule, immediate-release
- Trexall 10 MG; 15 MG; 5 MG; 7.5 MG; tablet
- Xatmep 2.5 MG/ML; oral solution

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