Rituxan Hycela™ (rituximab/hyaluronidase)

Humana

Pharmacy Coverage Policy

Effective Date: January 01, 2021
Revision Date: April 27, 2022
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Line of Business: Medicaid - Ohio
Policy Type: Prior Authorization

Products Affected
Rituxan Hycela subcutaneous solution

Listed Indications
Chronic Lymphocytic Leukemia
Follicular lymphoma
Diffuse large B cell lymphoma

Chronic Lymphocytic Leukemia	
Does the member meet all of the following criteria?	
Criteria #1	For Rituxan Hycela requests: Member has had prior treatment with intravenous rituximab and meets the clinical criteria below
Criteria #2	The member must have a diagnosis of chronic lymphocytic leukemia
Criteria #3	The member will be using Rituxan Hycela as monotherapy or in combination with fludarabine and cyclophosphamide
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	The member will be using Rituxan Hycela (rituximab/hyaluronidase) for the treatment of a non-malignant condition (e.g. rheumatoid arthritis)
Exclusion #2	The member will be using Rituxan Hycela (rituximab/hyaluronidase) as maintenance therapy for diffuse large B cell lymphoma (DLBCL)
Exclusion #3	The member will be using Rituxan Hycela (rituximab/hyaluronidase) as a single agent for first-line therapy in follicular lymphoma (FL)
Exclusion #4	The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkin's lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Exclusion #5	The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Approval Duration	
Initial	Rituxan Hycela (rituximab/hyaluronidase) will be approved in plan year duration or as deemed appropriate by clinical review.

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Follicular lymphoma	
Does the member meet all of the following criteria?	
Criteria #1	For Rituxan Hycela requests: Member has had prior treatment with intravenous rituximab and meets the clinical criteria below
Criteria #2	The member has a diagnosis of follicular lymphoma
Criteria #3	One of the following applies: ? Previously untreated disease and will be using Rituxan Hycela in combination with first line chemotherapy and, in patients achieving a complete or partial response to Rituxan Hycela in combination with chemotherapy, as single-agent maintenance therapy OR ? Non-progressing (including stable disease) disease, as a single agent after first line cyclophosphamide, vincristine, and prednisone chemotherapy

	OR ? Relapsed or refractory disease, as a single agent
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	The member will be using Rituxan Hycela (rituximab/hyaluronidase) for the treatment of a non-malignant condition (e.g. rheumatoid arthritis)
Exclusion #2	The member will be using Rituxan Hycela (rituximab/hyaluronidase) as maintenance therapy for diffuse large B cell lymphoma (DLBCL)
Exclusion #3	The member will be using Rituxan Hycela (rituximab/hyaluronidase) as a single agent for first-line therapy in follicular lymphoma (FL)
Exclusion #4	The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkin's lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Exclusion #5	The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Approval Duration	
Initial	Rituxan Hycela (rituximab/hyaluronidase) will be approved in plan year duration or as deemed appropriate by clinical review.

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Diffuse large B cell lymphoma

Does the member meet all of the following criteria?	
Criteria #1	For Rituxan Hycela requests: Member has had prior treatment with intravenous rituximab and meets the clinical criteria below
Criteria #2	The member has a diagnosis of diffuse large B cell lymphoma
Criteria #3	The member has previously untreated disease and will be using Rituxan Hycela in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone or with another anthracycline-based chemotherapy regimen
Does the member have any of the following exclusions? If yes, approval may not be appropriate. NOTE: Experimental/Investigational Use – Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.	
Exclusion #1	The member will be using Rituxan Hycela (rituximab/hyaluronidase) for the treatment of a non-malignant condition (e.g. rheumatoid arthritis)
Exclusion #2	The member will be using Rituxan Hycela (rituximab/hyaluronidase) as maintenance therapy for diffuse large B cell lymphoma (DLBCL)
Exclusion #3	The member will be using Rituxan Hycela (rituximab/hyaluronidase) as a single agent for first-line therapy in follicular lymphoma (FL)
Exclusion #4	The length of maintenance therapy exceeds 2 years for low-grade non-Hodgkin's lymphoma (e.g. follicular lymphoma, marginal zone lymphoma).
Exclusion #5	The length of maintenance therapy exceeds 2 years for chronic lymphocytic leukemia.
Approval Duration	
Initial	Rituxan Hycela (rituximab/hyaluronidase) will be approved in plan year duration or as deemed appropriate by clinical review.

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Background

This is a prior authorization policy about Rituxan Hycela (rituximab/hyaluronidase).

Black Box Warnings

- Hepatitis B virus (HBV) reactivation: In some cases resulting in fulminant hepatitis, hepatic failure, and death.
- Severe Mucocutaneous Reactions: Severe, including fatal, mucocutaneous reactions can occur in patients receiving rituximab.
- Progressive Multifocal Leukoencephalopathy (PML): JC virus infection resulting in PML and death can occur

Warnings and Precautions:

- Hypersensitivity and other administration reactions: Local cutaneous reactions may occur more than 24 hours after administration. Interrupt injection if severe reaction develops. Premedicate before injection.
- Tumor lysis syndrome: Administer aggressive intravenous hydration, antihyperuricemic agents, monitor renal function.
- Infections: Withhold and institute appropriate anti-infective therapy.
- Cardiac adverse reactions: Discontinue in case of serious or lifethreatening events.
- Renal toxicity: Discontinue in patients with rising serum creatinine or oliguria.
- Bowel obstruction and perforation: Consider and evaluate for abdominal pain, vomiting, or related symptoms.
- Immunizations: Live virus vaccinations prior to or during treatment not recommended.
- Embryo-Fetal toxicity: Can cause neonatal harm. Advise of potential risk to neonates and use of effective contraception.

Rituxan Hycela (rituximab/hyaluronidase), a murine/human monoclonal antibody, binds to the antigen CD20. This antigen is a hydrophobic transmembrane protein that is located on pre-B and mature B lymphocytes. It is also expressed on more than 90% of B-cell non-Hodgkin's lymphomas but not expressed on hematopoietic stem cells, pro-B cells, normal plasma cells, or other normal tissues.

The mechanism of antineoplastic action may involve mediation of B cell lysis by means of binding of the Fab domain of rituximab to the CD20 antigen on B lymphocytes and by recruitment of immune effector functions by the Fc domain. Cell lysis may be the result of complement-dependent cytotoxicity (CDC) and antibody-dependent cellular cytotoxicity (ADCC). In addition, the antibody has been shown to induce apoptosis in the DHL-4 human B-cell lymphoma line.

Rituxan Hycela (rituximab/hyaluronidase) is indicated for the treatment of:

- Relapsed or refractory, follicular lymphoma (FL) as a single agent.
- Previously untreated follicular lymphoma in combination with first-line chemotherapy and, in patients achieving a complete or partial response to rituximab in combination with chemotherapy, as single-agent maintenance therapy.
- Non-progressing (including stable disease) follicular lymphoma as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.
- Previously untreated diffuse large B-cell lymphoma (DLBCL) in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens.
- Previously untreated and previously treated chronic lymphocytic leukemia (CLL) in combination with fludarabine and cyclophosphamide (FC).

Rituximab/hyaluronidase is available as Rituxan Hycela in 1,400 mg rituximab and 23,400 Units hyaluronidase human per 11.7 mL and 1,600 mg rituximab and 26,800 Units hyaluronidase human per 13.4 mL single-use vials.

Provider Claim Codes

For medically billed requests, please visit www.humana.com/PAL. Select applicable Preauthorization and Notification List(s) for medical and procedural coding information.

Medical Terms

Rituxan Hycela; rituximab; chronic lymphocytic leukemia; CLL; follicular lymphoma; diffuse large B cell lymphoma; DLBCL; subcutaneous; pharmacy

References

Clinical Pharmacology [online database]. Tampa, FL: Gold Standard, Inc. URL: http://www.clinicalpharmacology.com. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically.

NCCN Drug and Biologics Compendium. Fort Washington, PA: National Comprehensive Cancer Network (NCCN); Updated periodically.

Rituxan Hycela (rituximab/hyaluronidase) Prescribing Information. Genentech. S. San Francisco, CA. June 2021.

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