Medical Policy:
Rituxan Hycela® (rituximab and hyaluronidase human) Subcutaneous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.125	August 23, 2023	January 1, 2021

Definitions

Rituxan Hycela (rituximab and hyaluronidase human): is a monoclonal antibody that targets the CD20antigen expressed on the surface of pre-B and mature B-lymphocytes. Upon binding to CD20, rituximab mediates B-cell lysis. Possible mechanisms of cell lysis include complement dependent cytotoxicity (CDC) and antibody dependent cell mediated cytotoxicity (ADCC). Hyaluronan is a polysaccharide found in the extracellular matrix of the subcutaneous tissue. It is depolymerized by the naturally occurring enzyme hyaluronidase. Unlike the stable structural components of the interstitial matrix, hyaluronan has a half-life of approximately 0.5 days. Hyaluronidase human increases permeability of the subcutaneous tissue by temporarily depolymerizing hyaluronan. In the doses administered, hyaluronidase human in Rituxan Hycela acts locally.

Rituxan Hycela (rituximab and hyaluronidase human) is FDA approved for the treatment of adult patients with follicular lymphoma, diffuse large B-cell lymphoma, and chronic lymphocytic leukemia. The approval provides patients a subcutaneous route of rituximab administration that shortens the administration time to 5 to 7 minutes as compared to intravenous infusion that can take several hours. This new product also provides for flat dosing.

Rituxan Hycela (rituximab and hyaluronidase human) is available as subcutaneous solution: 1,400mg-

23,400units/11.7mL and 1,600mg-26,800units/13.4mL (120 mg/1mL - 2000 units/1mL).

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

- Maintenance therapy may be renewed for up to a maximum of 2 years.

Dosing Limits [Medical Benefit]

A. Max Units (per dose and over time):

Follicular Lymphoma (FL):
• Relapsed-Refractory
  ○ 1,400 mg/23,400 U (140 billable units) weekly up to 7 doses
• Previously Untreated
  ○ 1,400 mg/23,400 U (140 billable units) every 21 days x 7 doses
  ○ 1,400 mg/23,400 U (140 billable units) every 8 weeks x 12 doses (maintenance)
• Non-progressing after first line CVP chemotherapy
  ○ 1,400 mg/23,400 U (140 billable units) weekly x 3 doses at 6 month intervals (up to a maximum of 16 doses.

Diffuse Large B-Cell Lymphoma (DLBCL): • 1,400 mg/23,400 U (140 billable units) every 14 or 21 days x 7 doses
Chronic Lymphocytic Leukemia (CLL): • 1,600 mg/26,800 U (160 billable units) every 28 days x 5 doses
B-Cell NHLs: • 1,400 mg/23,400 U (140 billable units) weekly for 3-7 doses in a 6-month period; **OR** • 1,400 mg/23,400 U (140 billable units) every 8 weeks (maintenance treatment)

Guideline

INITIAL APPROVAL CRITERIA

<u>For Commercial, Medicaid, and Medicare members:</u>

- Non-preferred agent: Rituxan Hycela
- Preferred agents: Ruxience and Truxima

Coverage is provided as follows:

- For <u>newly started Rituxan Hycela therapy,</u> for Commercial, Medicaid, and Medicare members:

  Coverage may be considered medically necessary as follows *(in addition to use supported by the National Comprehensive Cancer Network [NCCN] Clinical Practice Guidelines [NCCN Guidelines®] and/or NCCN Drugs & Biologics Compendium [NCCN Compendium®] with a recommendation of category level 1 or 2A*)*:

  - Patient has experienced a therapeutic failure or intolerance with the plan-preferred medications (Ruxience AND Truxima); **OR**
  - Rituxan Hycela is requested for an indication for which the plan-preferred agents (Ruxience or Truxima) have not been FDA-approved OR are not supported by NCCN Guidelines® or NCCN Compendium® with a recommendation of category level 1 or 2A; **AND**

- Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; **AND**
- Rituxan Hycela will not be used with intravenous chemotherapy agents; **AND**
- Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; **AND**
- Patient does not have a severe, active infection; **AND**
- Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; **AND**
- Patient is at least 18 years of age

1. **Follicular Lymphoma (FL)**
   A. The member has CD20 positive FL and Rituxan Hycela (rituximab and hyaluronidase human) is being used for **ONE** of the following:
      - In previously untreated FL in combination with first line chemotherapy **OR**
      - Treatment of relapsed or refractory disease as a single agent **OR**
      - Maintenance therapy in members achieving a complete or partial response to rituximab in combination with chemotherapy **OR**
      - Maintenance therapy in members with stable disease or better following first-line treatment with cyclophosphamide, vincristine, and prednisone (CVP).
2. **Diffuse Large B-Cell Lymphoma (DLBCL)**
   A. The member has CD20 positive DLBCL and previously untreated **AND**
   B. Rituxan Hycela (rituximab and hyaluronidase human) is being used as FIRST- LINE therapy in combination with cyclophosphamide, doxorubicin, vincristine, prednisone (CHOP) or other anthracycline-based chemotherapy regimens.

3. **Chronic Lymphocytic Leukemia (CLL)**
   A. Indicated, in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CLL.

Limitations

Rituxan Hycela (rituximab and hyaluronidase human) is not considered medically necessary when any of the following selection criteria is met:

1. Rituxan Hycela (rituximab and hyaluronidase human) is being used after disease progression with the same regimen or with standard Rituxan (rituximab)
2. Rituxan Hycela is not indicated for the treatment of non-malignant conditions (i.e. Rheumatoid Arthritis or ITP).
3. Rituxan (rituximab) is being used in members with severe, active infections.
4. Rituxan (rituximab) is being used without pretreatment medications.
5. Dosing exceeds single dose limit of Rituxan Hycela (rituximab and hyaluronidase human) 1600 mg rituximab and 26,800 units of hyaluronidase.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

1. Continuation of documented current and/or successful therapy with a non-preferred agent (Rituxan Hycela); **AND**
2. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: severe infusion reactions, tumor lysis syndrome (TLS), severe mucocutaneous reactions, progressive multifocal leukoencephalopathy (PML), viral hepatitis, serious bacterial, fungal, or viral infections, cardiac arrhythmias adverse reactions, renal toxicity, bowel obstruction or perforation, etc.; **AND**
3. Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
4. Patient has not exceeded dosing or duration limits.

Dosage/Administration

Prior to administering rituximab/hyaluronidase, all patients must have received at least 1 full dose of an IV infusion rituximab product without experiencing a severe adverse reaction. If a patient is not able to complete 1 full dose of an IV infusion rituximab product, continue the IV infusion rituximab product in subsequent cycles of therapy; a switch to rituximab/hyaluronidase may be made only after 1 full dose of an IV infusion rituximab product has been successfully administered. Rituxan Hycela (rituximab and hyaluronidase human) is for subcutaneous use only. Pre-medicate with acetaminophen and antihistamine before each dose; in addition, consider premedication with glucocorticoids to prevent hypersensitivity reactions.

Indication	Dose
FL/DLBCL	1,400 mg/23,400 Units (1,400 mg rituximab and 23,400 Units hyaluronidase human) subcutaneously according to recommended schedule.
(CLL)	1,600 mg/26,800 Units (1,600 mg rituximab and 26,800 Units hyaluronidase human) subcutaneously according to recommended schedule.
Administer specified volume into subcutaneous tissue of abdomen: •11.7 mL from 1,400 mg/23,400 Units vial over approximately 5 minutes. •13.4 mL from 1,600 mg/26,800 Units vial over approximately 7 minutes. •Observe 15 minutes following administration.	
Dosing Adjustments: Dose reductions of rituximab/hyaluronidase human are not recommended**.**	

Applicable Procedure Codes

Code	Description
J9311	Rituxan Hycela (hyaluronidase human, recombinant/rituximab), 10mg

Applicable NDCs

Code	Description

50242-0108-xx	Rituxan Hycela 1,400 mg rituximab/23,400 Units hyaluronidase human single-dose vial
50242-0109-xx	Rituxan Hycela 1,600 mg rituximab/26,800 Units hyaluronidase human single-dose vial

ICD-10 Diagnoses

Code	Description
B20	Human immunodeficiency virus [HIV] disease
C82.00	Follicular lymphoma grade I, unspecified site
C82.01	Follicular lymphoma grade I, lymph nodes of head, face and neck
C82.02	Follicular lymphoma, grade I, intrathoracic lymph nodes
C82.03	Follicular lymphoma grade I, intra-abdominal lymph nodes
C82.04	Follicular lymphoma grade I, lymph nodes of axilla and upper limb
C82.05	Follicular lymphoma grade I, lymph nodes of inguinal regional and lower limb
C82.06	Follicular lymphoma grade I, intrapelvic lymph nodes
C82.07	Follicular lymphoma grade I, spleen
C82.08	Follicular lymphoma grade I, lymph nodes of multiple sites
C82.09	Follicular lymphoma grade I, extranodal and solid organ sites
C82.10	Follicular lymphoma grade II, unspecified site
C82.11	Follicular lymphoma grade II, lymph nodes of head, face and neck
C82.12	Follicular lymphoma, grade II, intrathoracic lymph nodes
C82.13	Follicular lymphoma grade II, intra-abdominal lymph nodes
C82.14	Follicular lymphoma grade II, lymph nodes of axilla and upper limb
C82.15	Follicular lymphoma grade II, lymph nodes of inguinal region and lower limb
C82.16	Follicular lymphoma grade II, intrapelvic lymph nodes
C82.17	Follicular lymphoma grade II, spleen
C82.18	Follicular lymphoma grade II, lymph nodes of multiple sites
C82.19	Follicular lymphoma grade II, extranodal and solid organ sites
C82.20	Follicular lymphoma grade III, unspecified, unspecified site
C82.21	Follicular lymphoma grade III, unspecified, lymph nodes of head, face and neck
C82.22	Follicular lymphoma, grade III, unspecified, intrathoracic lymph nodes
C82.23	Follicular lymphoma grade III, unspecified, intra-abdominal lymph nodes
C82.24	Follicular lymphoma grade III, unspecified, lymph nodes of axilla and upper limb
C82.25	Follicular lymphoma grade III, unspecified, lymph nodes of inguinal region and lower limb
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen
C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.26	Follicular lymphoma grade III, unspecified, intrapelvic lymph nodes
C82.27	Follicular lymphoma grade III, unspecified, spleen

C82.28	Follicular lymphoma grade III, unspecified, lymph nodes of multiple sites
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organ sites
C82.30	Follicular lymphoma grade IIIa, unspecified site
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck
C82.32	Follicular lymphoma, grade IIIa, intrathoracic lymph nodes
C82.33	Follicular lymphoma grade IIIa, intra-abdominal lymph nodes
C82.34	Follicular lymphoma grade IIIa, lymph nodes of axilla and upper limb
C82.35	Follicular lymphoma grade IIIa, lymph nodes of inguinal region and lower limb
C82.36	Follicular lymphoma grade IIIa, intrapelvic lymph nodes
C82.37	Follicular lymphoma grade IIIa, spleen
C82.38	Follicular lymphoma grade IIIa, lymph nodes of multiple sites
C82.39	Follicular lymphoma grade IIIa, extranodal and solid organ sites
C82.40	Follicular lymphoma grade IIIb, unspecified site
C82.41	Follicular lymphoma grade IIIb, lymph nodes of head, face and neck
C82.42	Follicular lymphoma, grade IIIb, intrathoracic lymph nodes
C82.43	Follicular lymphoma grade IIIb, intra-abdominal lymph nodes
C82.44	Follicular lymphoma grade IIIb, lymph nodes of axilla and upper limb
C82.45	Follicular lymphoma grade IIIb, lymph nodes of inguinal region and lower limb
C82.46	Follicular lymphoma grade IIIb, intrapelvic lymph nodes
C82.47	Follicular lymphoma grade IIIb, spleen
C82.48	Follicular lymphoma grade IIIb, lymph nodes of multiple sites
C82.49	Follicular lymphoma grade IIIb, extranodal and solid organ sites
C82.50	Diffuse follicle center lymphoma, unspecified site
C82.51	Diffuse follicle center lymphoma, lymph nodes of head, face and neck
C82.52	Diffuse follicle center lymphoma, intrathoracic lymph nodes
C82.53	Diffuse follicle center lymphoma, intra-abdominal lymph nodes
C82.54	Diffuse follicle center lymphoma, lymph nodes of axilla and upper limb
C82.55	Diffuse follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.56	Diffuse follicle center lymphoma, intrapelvic lymph nodes
C82.57	Diffuse follicle center lymphoma, spleen
C82.58	Diffuse follicle center lymphoma, lymph nodes of multiple sites
C82.59	Diffuse follicle center lymphoma, extranodal and solid organ sites
C82.60	Cutaneous follicle center lymphoma, unspecified site
C82.61	Cutaneous follicle center lymphoma, lymph nodes of head, face and neck
C82.62	Cutaneous follicle center lymphoma, intrathoracic lymph nodes
C82.63	Cutaneous follicle center lymphoma, intra-abdominal lymph nodes
C82.64	Cutaneous follicle center lymphoma, lymph nodes of axilla and upper limb
C82.65	Cutaneous follicle center lymphoma, lymph nodes of inguinal region and lower limb
C82.66	Cutaneous follicle center lymphoma, intrapelvic lymph nodes
C82.67	Cutaneous follicle center lymphoma, spleen
C82.68	Cutaneous follicle center lymphoma, lymph nodes of multiple sites
C82.69	Cutaneous follicle center lymphoma, extranodal and solid organ sites
C82.80	Other types of follicular lymphoma, unspecified site
C82.81	Other types of follicular lymphoma, lymph nodes of head, face and neck
C82.82	Other types of follicular lymphoma, intrathoracic lymph nodes
C82.83	Other types of follicular lymphoma, intra-abdominal lymph nodes

C82.84	Other types of follicular lymphoma, lymph nodes of axilla and upper limb
C82.85	Other types of follicular lymphoma, lymph nodes of inguinal region and lower limb
C82.86	Other types of follicular lymphoma, intrapelvic lymph nodes
C82.87	Other types of follicular lymphoma, spleen
C82.88	Other types of follicular lymphoma, lymph nodes of multiple sites
C82.89	Other types of follicular lymphoma, extranodal and solid organ sites
C82.90	Follicular lymphoma, unspecified, unspecified site
C82.91	Follicular lymphoma, unspecified, lymph nodes of head, face and neck
C82.92	Follicular lymphoma, unspecified, intrathoracic lymph nodes
C82.93	Follicular lymphoma, unspecified, intra-abdominal lymph nodes
C82.94	Follicular lymphoma, unspecified, lymph nodes of axilla and upper limb
C82.95	Follicular lymphoma, unspecified lymph nodes of inguinal region and lower limb
C82.96	Follicular lymphoma, unspecified, intrapelvic lymph nodes
C82.97	Follicular lymphoma, unspecified, spleen
C82.98	Follicular lymphoma, unspecified, lymph nodes of multiple sites
C82.99	Follicular lymphoma, unspecified, extranodal and solid organ sites
C83.00	Small cell B-cell lymphoma, unspecified site
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face and neck
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes
C83.07	Small cell B-cell lymphoma, spleen
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites
C83.10	Mantle cell lymphoma, unspecified site
C83.11	Mantle cell lymphoma, lymph nodes of head, face and neck
C83.12	Mantle cell lymphoma, intrathoracic lymph nodes
C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes
C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb
C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb
C83.16	Mantle cell lymphoma, intrapelvic lymph nodes
C83.17	Mantle cell lymphoma, spleen
C83.17	Mantle cell lymphoma, spleen
C83.18	Mantle cell lymphoma, lymph nodes of multiple sites
C83.19	Mantle cell lymphoma, extranodal and solid organ sites
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck
C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes
C83.33	Diffuse large B-cell lymphoma intra-abdominal lymph nodes
C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb
C83.35	Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C83.36	Diffuse large B-cell lymphoma intrapelvic lymph nodes
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites

C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.70	Burkitt lymphoma, unspecified site
C83.71	Burkitt lymphoma, lymph nodes of head, face, and neck
C83.72	Burkitt lymphoma, intrathoracic lymph nodes
C83.73	Burkitt lymphoma, intra-abdominal lymph nodes
C83.74	Burkitt lymphoma, lymph nodes of axilla and upper limb
C83.75	Burkitt lymphoma, lymph nodes of inguinal region and lower limb
C83.76	Burkitt lymphoma, intrapelvic lymph nodes
C83.77	Burkitt lymphoma, spleen
C83.78	Burkitt lymphoma, lymph nodes of multiple sites
C83.79	Burkitt lymphoma, extranodal and solid organ sites
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites
C83.90	Non-follicular (diffuse) lymphoma, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of head, face, and neck
C83.37	Diffuse large B-cell lymphoma, spleen
C83.38	Diffuse large B-cell lymphoma lymph nodes of multiple sites
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.70	Burkitt lymphoma, unspecified site
C83.71	Burkitt lymphoma, lymph nodes of head, face, and neck
C83.72	Burkitt lymphoma, intrathoracic lymph nodes
C83.73	Burkitt lymphoma, intra-abdominal lymph nodes
C83.74	Burkitt lymphoma, lymph nodes of axilla and upper limb
C83.75	Burkitt lymphoma, lymph nodes of inguinal region and lower limb
C83.76	Burkitt lymphoma, intrapelvic lymph nodes
C83.77	Burkitt lymphoma, spleen
C83.78	Burkitt lymphoma, lymph nodes of multiple sites
C83.79	Burkitt lymphoma, extranodal and solid organ sites
C83.80	Other non-follicular lymphoma, unspecified site
C83.81	Other non-follicular lymphoma, lymph nodes of head, face and neck
C83.82	Other non-follicular lymphoma, intrathoracic lymph nodes
C83.83	Other non-follicular lymphoma, intra-abdominal lymph nodes
C83.84	Other non-follicular lymphoma, lymph nodes of axilla and upper limb
C83.85	Other non-follicular lymphoma, lymph nodes of inguinal region and lower limb
C83.86	Other non-follicular lymphoma, intrapelvic lymph nodes
C83.87	Other non-follicular lymphoma, spleen
C83.88	Other non-follicular lymphoma, lymph nodes of multiple sites
C83.89	Other non-follicular lymphoma, extranodal and solid organ sites

C83.90	Non-follicular (diffuse) lymphoma, unspecified site
C83.91	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of head, face, and neck
C83.92	Non-follicular (diffuse) lymphoma, unspecified intrathoracic lymph nodes
C83.93	Non-follicular (diffuse) lymphoma, unspecified intra-abdominal lymph nodes
C83.94	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of axilla and upper limb
C83.95	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of inguinal region and lower limb
C83.96	Non-follicular (diffuse) lymphoma, unspecified intrapelvic lymph nodes
C83.97	Non-follicular (diffuse) lymphoma, unspecified spleen
C83.98	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of multiple sites
C83.99	Non-follicular (diffuse) lymphoma, unspecified extranodal and solid organ sites
C85.20	Mediastinal (thymic) large B-cell lymphoma, unspecified site
C85.21	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of head, face and neck
C85.22	Mediastinal (thymic) large B-cell lymphoma, intrathoracic lymph nodes
C85.23	Mediastinal (thymic) large B-cell lymphoma, intra-abdominal lymph nodes
C85.24	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of axilla and upper limb
C85.25	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of inguinal region and lower limb
C85.26	Mediastinal (thymic) large B-cell lymphoma, intrapelvic lymph nodes
C85.27	Mediastinal (thymic) large B-cell lymphoma, spleen
C85.28	Mediastinal (thymic) large B-cell lymphoma, lymph nodes of multiple sites
C85.29	Mediastinal (thymic) large B-cell lymphoma, extranodal and solid organ sites
C85.80	Other specified types of non-Hodgkin lymphoma, unspecified site
C85.81	Other specified types of non-Hodgkin lymphoma, lymph nodes of head, face and neck
C85.82	Other specified types of non-Hodgkin lymphoma, intrathoracic lymph nodes
C85.83	Other specified types of non-Hodgkin lymphoma, intra-abdominal lymph nodes
C85.84	Other specified types of non-Hodgkin lymphoma, lymph nodes of axilla and upper limb
C85.85	Other specified types of non-Hodgkin lymphoma, lymph nodes of inguinal region of lower limb
C85.86	Other specified types of non-Hodgkin lymphoma, intrapelvic lymph nodes
C85.87	Other specified types of non-Hodgkin lymphoma, spleen
C85.88	Other specified types of non-Hodgkin lymphoma, lymph nodes of multiple sites
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites
C88.4	Extranodal marginal zone B-cell lymphoma of mucosa-associated lymphoid tissue (MALT-lymphoma)
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse
D36.0	Benign neoplasm of lymph nodes
D47.Z1	Post-transplant lymphoproliferative disorder (PTLD)
D47.Z2	Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue – Castleman Disease
R59.0	Localized enlarged lymph nodes
R59.1	Generalized enlarged lymph nodes
R59.9	Enlarged lymph nodes, unspecified
Z85.72	Personal history of non-Hodgkin lymphomas

Revision History

Company(ies)	DATE	REVISION

<table>
<tr><td>EmblemHealth & ConnectiCare</td><td>8/23/2023</td><td>Annual Review:
For <u>newly started Rituxan Hycela therapy,</u> for Commercial, Medicaid, and Medicare members: Added:
○ “Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; AND
○ Rituxan Hycela will not be used with intravenous chemotherapy agents; AND
○ Patient has not received a live vaccine within 28 days prior to starting treatment and live vaccines will not be administered concurrently while on treatment; AND
○ Patient does not have a severe, active infection; AND
○ Patient has been screened for the presence of hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy and patients with evidence of current or prior HBV infection will be monitored for HBV reactivation during treatment; AND
○ Patient is at least 18 years of age”
<u>Chronic Lymphocytic Leukemia (CLL) Initial Criteria: Removed:</u>
A. “The member has stage III-IV CD 20 positive CLL, or if Stage 0-II disease, member must have bulky adenopathy, splenomegaly, OR systemic symptoms AND
B. Rituxan Hycela (rituximab and hyaluronidase human) is being used as FIRST-LINE therapy in combination with fludarabine and cyclophosphamide (FC).”
Added:
B. “Indicated, in combination with fludarabine and cyclophosphamide (FC), for the treatment of adult patients with previously untreated and previously treated CLL.”
Removed Codes:
<table><tr><td>J9999</td><td>Not otherwise classified, antineoplastic drugs</td></tr><tr><td>C9467</td><td>Injection, rituximab and hyaluronidase, 10 mg</td></tr></table></td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>1/11/2023</td><td>Transferred to New Template</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>12/19/2020</td><td>Clarifications:
• Step therapy will apply to NEW starts only
• NCCN-supported use (with 1 or 2A recommendation) will be covered
Renewal criteria updated:
• Removed: “Patient continues to meet criteria identified above”
Added coverage: “Continuation of documented current and/or successful therapy with a non-preferred agent (Rituxan Hycela)”</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>11/2/2020</td><td>Effective 01/01/2021 Member must fail trial of Ruxience AND Truxima, prior to using Rituxan Hycela (Medicare members are subject to this step therapy).</td></tr>
<tr><td>EmblemHealth & ConnectiCare</td><td>03/31/2020</td><td>Added to the Initial Approval Criteria: Effective 07/01/2020, Ruxience and Truxima are the preferred agents for Commercial and Medicaid members. Failed trial of Ruxience AND Truxima for FDA approved indications prior to using Rituxan Hycela (Only Commercial and</td></tr>
</table>

		Medicaid members are subject to this step therapy).
EmblemHealth & ConnectiCare	1/1/2019	Added J9311, Rituxan Hycela (hyaluronidase human, recombinant/rituximab), 10mg

References

1. Rituxan Hycela (rituximab and hyaluronidase human) prescribing information. Genentech, Inc. South San Francisco, CA 2017. Last Revision April 2018.
2. Clinical Pharmacology Elsevier Gold Standard. 2017.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2017.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium.2017.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2017.