

# 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

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as "EmblemHealth"), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

#### **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
  - o 1,400 mg/23,400 U (140 billable units) weekly up to 7 doses
- Previously Untreated
  - o 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**

#### For Commercial, Medicaid, and Medicare members:

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

#### Coverage is provided as follows:

• For newly started Rituxan Hycela therapy, 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
- o 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
- o 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. <u>Diffuse Large B-Cell Lymphoma (DLBCL)</u>

- 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:

- 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. Premedicate 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 speci	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		
C82.29	Follicular lymphoma grade III, unspecified, extranodal and solid organisites  Follicular lymphoma grade IIIa, unspecified site		
C82.31	Follicular lymphoma grade IIIa, lymph nodes of head, face and neck		
C82.32	Follicular lymphoma, grade Illa, 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		

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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  C83.18 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 intrathoracic lymph nodes  C83.32 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	C83.07	Small cell B-cell lymphoma, spleen		
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  C83.18 Mantle cell lymphoma, spleen  C83.19 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	C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites		
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 C83.18 Mantle cell lymphoma, spleen C83.19 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	C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites		
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 intrathoracic lymph nodes C83.32 Diffuse large B-cell lymphoma intrathoracic lymph nodes C83.34 Diffuse large B-cell lymphoma intra-abdominal lymph nodes C83.35 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.36 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb C83.37 Diffuse large B-cell lymphoma intrapelvic lymph nodes C83.37 Diffuse large B-cell lymphoma, spleen	C83.10	Mantle cell lymphoma, unspecified site		
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 C83.18 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	C83.11			
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 C83.18 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	C83.12	Mantle cell lymphoma, intrathoracic lymph nodes		
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 C83.18 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	C83.13	Mantle cell lymphoma, intra-abdominal lymph nodes		
C83.16 Mantle cell lymphoma, intrapelvic lymph nodes 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	C83.14	Mantle cell lymphoma, lymph nodes of axilla and upper limb		
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	C83.15	Mantle cell lymphoma, lymph nodes of inguinal region and lower limb		
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	C83.16	Mantle cell lymphoma, intrapelvic lymph nodes		
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				
C83.19 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	C83.17	Mantle cell lymphoma, spleen		
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	C83.18			
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	C83.19			
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	C83.30			
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	C83.31	Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck		
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	C83.32	Diffuse large B-cell lymphoma intrathoracic lymph nodes		
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				
C83.36 Diffuse large B-cell lymphoma intrapelvic lymph nodes C83.37 Diffuse large B-cell lymphoma, spleen	C83.34	Diffuse large B-cell lymphoma lymph nodes of axilla and upper limb		
C83.37 Diffuse large B-cell lymphoma, spleen	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		
C83.38 Diffuse large B-cell lymphoma lymph nodes of multiple sites	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		
C83.90	Non-follicular (diffuse) lymphoma, unspecified lymph nodes of head, face, and neck		
C83.92	Non-follicular (diffuse) lymphoma, unspecified intrathoracic lymph nodes		
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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
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EmblemHealth &	8/23/2023	Annual Review:	
ConnectiCare	3, 23, 2323	For <u>newly started Rituxan Hycela therapy,</u> for Commercial, Medicaid, and	
Comiccicare		Medicare members: Added:	
		<ul> <li>"Patient has received at least one full dose of a rituximab product by intravenous infusion prior to initiating therapy; AND</li> <li>Rituxan Hycela will not be used with intravenous chemotherapy agents; AND</li> <li>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</li> <li>Patient does not have a severe, active infection; AND</li> <li>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</li> <li>Patient is at least 18 years of age"</li> </ul>	
		Chronic Lymphocytic Leukemia (CLL) Initial Criteria: Removed:	
		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:	
		J9999 Not otherwise classified, antineoplastic drugs	
		C9467 Injection, rituximab and hyaluronidase, 10 mg	
EmblemHealth & ConnectiCare	1/11/2023	Transferred to New Template	
EmblemHealth & ConnectiCare	12/19/2020	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)"	
EmblemHealth &	11/2/2020	Effective 01/01/2021 Member must fail trial of Ruxience AND Truxima,	
ConnectiCare	,,	prior to using Rituxan Hycela (Medicare members are subject to this step therapy).	
EmblemHealth & ConnectiCare	03/31/2020	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	

		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.