Policy Title:	Rituxan Hycela (rituximab and hyaluronidase human) (Subcutaneous)		
		Department:	PHA
Effective Date:	01/01/2020		
Review Date:	12/20/2019, 1/29/20		
Revision Date:	12/20/2019, 1/29/20		

Purpose: To support safe, effective and appropriate use of Rituxan Hycela (rituximab and hyaluronidase human).

Scope: Medicaid, Exchange, Medicare-Medicaid Plan (MMP)

Policy Statement:

Rituxan Hycela (rituximab and hyaluronidase human) is covered under the Medical Benefit when used within the following guidelines. Use outside of these guidelines may result in non-payment unless approved under an exception process.

Procedure:

Coverage of Rituxan Hycela (rituximab and hyaluronidase human) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria:

- Patient must be screened for Hepatitis B virus (HBV) infection (i.e., HBsAg and anti-HBc) prior to initiating therapy; AND
- Patient is CD20-positive; AND
- Patient has received at least one full dose of a rituximab product by intravenous infusion; AND
- For new start to therapy, patient must have failure or intolerable side effects to a rituximab biosimilar product. Patients that are currently on treatment with Rituxan Hycela (rituximab and hyaluronidase human) can remain on treatment OR for MMP members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements; AND
- Coverage is provided in the following conditions:
    - Chronic lymphocytic leukemia/Small lymphocytic lymphoma (CLL/SLL)
    - Non-Hodgkin's lymphomas (NHL)
    - Follicular Lymphoma (FL)
    - Diffuse Large B-Cell Lymphoma (DLBCL)
    - High Grade B-Cell Lymphomas

- AIDS-related B-Cell Lymphoma
- Burkitt Lymphoma
- Castleman's Disease
- Gastric & Non-gastric MALT Lymphoma
- Mantle Cell Lymphoma
- Nodal & Splenic Marginal Zone Lymphoma
- Histologic transformation of Marginal Zone Lymphoma to Diffuse Large B-Cell Lymphoma
- Post-transplant lymphoproliferative disorder (PTLD)
- Primary Cutaneous B-Cell Lymphoma
    - Used for generalized (skin only), marginal zone or follicle center disease

Continuation of Therapy Criteria:

- Patient continues to meet initial criteria; AND
- 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 adverse reactions, renal toxicity, bowel obstruction or perforation, etc.; AND
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread

Coverage durations:

- Initial coverage: 6 months, unless otherwise specified
- Continuation of therapy coverage: 6 months, unless otherwise specified; maintenance therapy may be renewed for up to a maximum of 2 years

*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable.***

Dosage/Administration:

Indication	Dose	Maximum dose (1 billable unit = 10 mg)
Follicular Lymphoma (FL)	1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA, according to the following schedules: **Relapsed or Refractory:** • Weekly for 3 or 7 weeks (i.e., 4 or 8 weeks in total) **Retreatment for Relapsed or Refractory**: • Weekly for 3 weeks (i.e., 4 weeks in total)	**Relapsed-Refractory**: • 140 billable units weekly up to 7 doses

	Previously Untreated: • Day 1 of Cycles 2–8 of chemotherapy (every 21 days), for up to 7 cycles (i.e., up to 8 cycles in total). In patients with complete or partial response, initiate maintenance treatment 8 weeks following completion of initial therapy. Administer Rituxan Hycela every 8 weeks for 12 doses. **Non-progressing after first line CVP chemotherapy**: • Following completion of 6–8 cycles of chemotherapy, administer once weekly for 3 weeks (i.e., 4 weeks in total) at 6 month intervals to a maximum of 16 doses.	**Previously Untreated:** • 140 billable units every 21 days x 7 doses • 140 billable units every 8 weeks x 12 doses (maintenance) **Non-progressing after first line CVP chemotherapy**: • 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 Units subcutaneously, at a fixed dose, irrespective of patient's BSA. • Administer on Day 1 of Cycles 2–8 of chemotherapy for up to 7 cycles (i.e., up to 6-8 cycles in total). Cycle length is 21 days.	• 140 billable units every 21 days x 7 doses
Chronic Lymphocytic Leukemia (CLL)	1,600 mg/26,800 Units subcutaneously, at a fixed dose, irrespective of patient's BSA. • Administer on Day 1 of Cycles 2–6 (every 28 days) for a total of 5 cycles (i.e., 6 cycles in total). Cycle length is 28 days.	• 160 billable units every 28 days x 5 doses
B-Cell NHLs	1,400 mg/23,400 Units subcutaneously, at a fixed dose, irrespective of patient's BSA. • Administer up to once weekly for 3-7 doses in a 6-month period; OR • Administer once every 8 weeks (maintenance treatment)	• 140 billable units weekly for 3-7 doses in a 6-month period; OR • 140 billable units every 8 weeks (maintenance treatment)

Investigational use: All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

Applicable Codes:
Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all inclusive. Requests received with codes from

tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT codes are:

HCPCS/CPT Code	Description
J9311	Injection, rituximab 10 mg and hyaluronidase

References:

1. Rituxan Hycela [package insert]. South San Francisco, CA; Genentech, Inc; April 2018. Accessed February 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) rituximab and hyaluronidase human. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed February 2019.
3. National Government Services, Inc. Local Coverage Article: Rituximab (Rituxan®) (effective 2010) - Related to LCD L33394 (A52452). Centers for Medicare & Medicaid Services, Inc. Updated on 12/19/2018 with effective date of 01/01/2019. Accessed February 2019.