Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 165.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Rituxan Hycela (rituximab/hyaluronidase)

I. Policy:
Rituxan Hycela (rituximab/hyaluronidase)

II. Purpose/Objective:
To provide a policy of coverage regarding Rituxan Hycela (rituximab/hyaluronidase)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Rituxan Hycela is a combination product containing rituximab and hyaluronidase. Rituximab is a monoclonal antibody directed against the CD20 antigen on the surface of pre-B and mature B-lymphocytes. CD20 regulates cell cycle initiation; and, possibly, functions as a calcium channel. Rituximab binds to the antigen on the cell surface, activating complement-dependent B-cell cytotoxicity; and to human Fc receptors, mediating cell killing through an antibody-dependent cellular toxicity. Hyaluronidase increases the absorption rate of rituximab-containing products by increasing permeability of subcutaneous tissue through temporary depolymerization of hyaluronan

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Rituxan Hycela (rituximab/hyaluronidase) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Chronic Lymphocytic Leukemia (CLL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Chronic Lymphocytic Leukemia (CLL) **AND**
- Medical record documentation that Rituxan Hycela is being given in combination with fludarabine and cyclophosphamide **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) cycle of intravenous rituximab

Note: The FDA-approved dosage for CLL is 1,600mg/26,800units of Rituxan Hycela per dose.

Diffuse Large B-Cell Lymphoma (DLBCL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Diffuse Large B-Cell Lymphoma (DLBCL) **AND**
- Medical record documentation that member has NOT received prior treatment for DLBCL **AND**
- Medical record documentation that Rituxan Hycela is being given in combination with cyclophosphamide, doxorubicin, vincristine, and prednisone (CHOP) or other anthracycline-based chemotherapy regimen **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) cycle of intravenous rituximab

Note: The FDA-approved dosage for DLBCL is 1,400mg/23,400units of Rituxan Hycela per dose.

Follicular Lymphoma (FL)

- Prescription written by a hematologist/oncologist **AND**
- Medical record documentation of a diagnosis of Follicular Lymphoma (FL) **AND**
- Medical record documentation that member has received and tolerated a minimum of one (1) full dose of intravenous rituximab

Note: The FDA-approved dosage for FL is 1,400mg/23,400units of Rituxan Hycela per dose. The schedule of Rituxan Hycela is specific to diagnosis.

Note: Rituxan Hycela has not been studied in and is not FDA-approved for non-malignant conditions. For this reason, Rituxan Hycela is considered off-label and investigational for use in non-malignant conditions and is not covered.

QUANTITY LIMIT: Authorizations should be entered by **GPI 14** with the following quantity limits (authorized strength will be dependent on diagnosis):

- Rituxan Hycela 1,400mg/23,400units: **4 vials (46.8mL) per 28 days**
- Rituxan Hycela 1,600mg/26,800units: **1 vial (13.4mL) per 28 days**

AUTHORIZATION DURATION: Initial approval will be for **6 months** or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional **12 months** or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Requests exceeding the maximum FDA-approved treatment duration (listed below) will require the following:

- Medical record documentation of peer-reviewed literature citing well-designed clinical trials to indicate that the member's healthcare outcome will be improved by dosing beyond the FDA-approved treatment duration as listed in the chart below.

Indication	Maximum Treatment Duration
Follicular Lymphoma (FL)	
Relapsed or Refractory	7 Weeks
Retreatment for Relapsed or Refractory	3 Weeks
Previously Untreated	21 Weeks (Seven 21-day cycles) for induction, up to 2 years for maintenance
Non-progressing after first line CVP chemotherapy	2 Years (16 doses given once weekly for 4 weeks in 6-month intervals)
Diffuse Large B-Cell Lymphoma (DLBCL)	21 Weeks (Seven 21-day cycles)
Chronic Lymphocytic Leukemia (CLL)	5 Months (Five 28-day cycles)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 1/16/18

Revised: 2/27/18 (per DHS), 3/20/18 (added duration box), 4/24/18 (max duration updated), 11/29/22 (Medicaid PARP statement, LOB carve out, GPI 14, brand RTX delete), 10/26/23 (Medicaid business segment)

Reviewed: 2/28/19, 1/1/20, 1/1/21, 12/17/21