Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 113.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Gazyva (obinutuzumab)

I. Policy:
Gazyva (obinutuzumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Gazyva (obinutuzumab)

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:
Gazyva (obinutuzumab) is a monoclonal antibody that targets CD20 antigen that is expressed on the surface pf pre-B and mature B-cell lymphocytes.

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

Gazyva (obinutuzumab) will be considered medically necessary for all lines of business when all of the following criteria are met:

1. **Chronic Lymphocytic Leukemia (CLL)**
   - Prescribed by a hematologist/oncologist; **AND**
   - Medical record documentation of previously untreated chronic lymphocytic leukemia; **AND**
   - Medical record documentation that Gazyva will be used in combination with chlorambucil

   AUTHORIZATION DURATION for CLL: Initial approval will be for 12 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.

2. **Follicular Lymphoma**
   - Medical record documentation of a diagnosis of follicular lymphoma **AND**
     - For first line therapy:
       - Medical record documentation of previously untreated stage II bulky, III or IV follicular lymphoma **AND**
       - Medical record documentation that Gazyva will be used in combination with chemotherapy **OR**
       - Medical record documentation that the patient has achieved at least a partial remission of stage II bulky, III, or IV follicular lymphoma if previously treated with at least 6 cycles of Gazyva in combination with chemotherapy **AND**
       - Medical record documentation that Gazyva will be used as monotherapy

     - For second line or subsequent therapy:
       - Medical record documentation that the patient has relapsed after, or is refractory to, a rituximab-containing regimen **AND**
       - Medical record documentation that Gazyva is being used in combination with bendamustine **OR**
       - Medical record documentation that the patient achieved a complete response, partial response, or has stable disease after at least 6 cycles of Gazyva in combination with bendamustine **AND**
       - Medical record documentation that Gazyva will be used as monotherapy.

     ***Note:** In clinical trials for the treatment of stage II bulky, III or IV follicular lymphoma chemotherapy was defined as: CHOP (cyclophosphamide, doxorubicin, vincristine and prednisone); CVP (cyclophosphamide, vincristine and prednisone); or bendamustine

   AUTHORIZATION DURATION for follicular lymphoma: Initial approval will be 6 months for this indication. The following criteria should apply to reauthorization requests for Gazyva:
   - Medical record documentation that the patient achieved a complete response, partial response, or has stable disease after 6 cycles of Gazyva + bendamustine therapy OR after 6 cycles of Gazyva + chemotherapy **AND**
   - Documentation that Gazyva will be used as monotherapy.

   Subsequent authorization duration should be 24 months as data does not extend past this point.

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: 3/18/14

Revised: 3/24/15 (formatting, additional criteria added, revised authorization criteria), 5/17/16 (added follicular lymphoma indication), 1/16/18 (FL first line indication), per DHS 2/28/18, 8/17/22 (Medicaid PARP statement), 8/14/23 (LOB carve out, Medicaid business segment)

Reviewed: 3/2016, 5/16/17, 10/31/18, 8/29/19, 8/26/20, 8/19/21