BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

GLEOSTINE® (lomustine) oral

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

- **Criteria for initial therapy:** Gleostine (lomustine) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met:

  1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Oncologist.

  2. Individual is 18 years of age or older.

  3. Individual has a confirmed diagnosis of **ONE** of the following:
     a. **Primary and metastatic brain tumors** following appropriate surgical and/or radiotherapeutic procedures

     b. **Hodgkin lymphoma** as a component of combination chemotherapy agents for disease that has progressed following initial chemotherapy

c. Other request for a specific oncologic direct treatment use that is found and listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

4. Pulmonary function tests have been completed before initiation of treatment with continued monitoring as clinically appropriate.

Initial approval duration:
ONLY enough dosage units for a single dose every 6 weeks
NO MORE than **ONE** dose to be dispensed at a time

- **Criteria for continuation of coverage (renewal request):** Gleostine (lomustine) is considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy**):

1. Individual continues to be seen by a physician specializing in the patient's diagnosis or is in consultation with an Oncologist.

2. Individual's condition has responded while on therapy with response defined as **ALL** of the following:
   a. Documented evidence of disease stability
   b. No evidence of disease progression

3. Individual has been adherent with the medication.

4. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
   a. Pulmonary infiltrates and/or pulmonary fibrosis
   b. Hepatotoxicity
   c. Nephrotoxicity
   d. Myelosuppression

Renewal duration:
ONLY enough dosage units for a single dose every 6 weeks
NO MORE than **ONE** dose to be dispensed at a time

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. **Off-Label Use of Non-Cancer Medications**

2. **Off-Label Use of Cancer Medications**

Description:

Gleostine (lomustine) is indicated for the treatment of patients with primary and metastatic brain tumors following appropriate surgical and/or radiotherapeutic procedures and it is indicated as a component of combination

chemotherapy for the treatment of patients with Hodgkin's lymphoma whose disease has progressed following initial chemotherapy.

Resources:

Gleostine (lomustine) product information, revised by NextSource Biotechnology, LLC. 09-2018. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed August 03, 2022.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology: Central Nervous System Cancers. Version 01.2022– Updated June 02, 2022. Accessed August 03, 2022.

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.