## Clinical Policy: Lomustine (Gleostine)

Reference Number: PA.CP.PHAR.507
Effective Date: 10/2020
Last Review Date: 10/2025

**Description**
Lomustine (Gleostine®) is a nitrosourea and an alkylating agent.

**FDA Approved Indication(s)**
Gleostine is indicated for the treatment of patients with:

- Brain tumors, primary and metastatic, following appropriate surgical and/or radiotherapeutic procedures;
- Hodgkin's lymphoma in combination with other chemotherapies, following disease progression with initial chemotherapy.

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Gleostine is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Brain Tumors** (must meet all)**:**

1. Diagnosis of brain tumor;
2. Prescribed by or in consultation with an oncologist;
3. For brand Gleostine requests, member must use generic lomustine, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. Request meets one of the following (a or b):
   a. Dose does not exceed 130 mg/m$^2$ every 6 weeks.
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Approval duration: 12 months**

**B. Hodgkin's Lymphoma** (must meet all)**:**

1. Diagnosis of Hodgkin's lymphoma;
2. Prescribed by or in consultation with an oncologist or hematologist;
3. Failure of an initial chemotherapy regimen *(see Appendix B for examples)*, unless contraindicated or clinically significant adverse effects are experienced;
4. Prescribed in combination with chemotherapy;
5. For brand Gleostine requests, member must use generic lomustine, if available, unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):
   a. Dose does not exceed 130 mg/m$^2$ every 6 weeks.
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(prescriber must submit supporting evidence).*

**Approval duration: 12 months**

**C. Other diagnoses/indications**
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## II. Continued Therapy

**A. All Indications in Section I** (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. For brand Gleostine requests, member must use generic lomustine, if available, unless contraindicated or clinically significant adverse effects are experienced;
4. If request is for a dose increase, request meets one of the following (a or b):
   a. New dose does not exceed 130 mg/m$^2$ every 6 weeks;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   **Approval duration: Duration of request or 6 months (whichever is less)**; or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

## III. Diagnoses/Indications for which coverage is NOT authorized:

**A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*
FDA: Food and Drug Administration
NCCN: National Comprehensive Cancer Network

*Appendix B: Therapeutic Alternatives*
*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **Hodgkin's Lymphoma**<br>*Examples of primary systemic therapies:*<br>• ABVD (doxorubicin, bleomycin, vinblastine, dacarbazine)<br>• BEACOPP (bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone)<br>• BrECADD (brentuximab vedotin, etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone)<br>• BV + AVD (brentuximab vedotin, doxorubicin, vinblastine, dacarbazine)<br>• nivolumab-AVD (Opdivo® [nivolumab] + doxorubicin, vinblastine, dacarbazine)<br>• R-CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone + rituximab)<br>CVbP + rituximab (cyclophosphamide, vinblastine, prednisolone + rituximab) | Varies | Varies |

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): none reported
- Boxed warning(s):
  - Delayed myelosuppression
  - Risk of overdosage.

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Brain tumors, Hodgkin's lymphoma | 130 mg/m$^2$ PO one time every 6 weeks | 130 mg/m$^2$ every 6 weeks |

## VI. Product Availability

Capsules: 10 mg, 40 mg, 100 mg

## VII. References

1. Gleostine Prescribing Information. Miami, FL: NextSource Biotechnology; September 2018. Available at: www.gleostine.com. Accessed July 17, 2025.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 17, 2025.
3. National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed July 17, 2025.

4. National Comprehensive Cancer Network. Hodgkin Lymphoma Version 2.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Accessed July 17, 2025.
5. Clinical Pharmacology [database online]. Tampa, FL: Elsevier, Inc.; 2025. Available at: https://www.clinicalkey.com/pharmacology/.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 10/2020 |
| 4Q 2021 annual review: for brain tumors, removed temozolomide re-direction per SDC; for Hodgkin's lymphoma, added requirement for combination use per FDA label; references reviewed and updated. | 10/2021 |
| 4Q 2022 annual review: no significant changes; revised FDA approved indication to mirror prescribing information; added redirection to generic equivalents when available; references reviewed and updated. | 10/2022 |
| 4Q 2023 annual review: no significant changes; references reviewed and updated. | 10/2023 |
| 4Q 2024 annual review: no significant changes; references reviewed and updated. | 10/2024 |
| 4Q 2025 annual review: for all indications, extended initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; references reviewed and updated. | 10/2025 |