Clinical Policy: Lomustine (Gleostine)

Reference Number: PA.CP.PHAR.507
Effective Date: 10/2020
Last Review Date: 10/2023 Revision Log

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: 6 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: 6 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.LTSS.PHAR.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.LTSS.PHAR.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 for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Temozolomide (Temodar®)	Brain Tumors	200 mg/m^2/day

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Glioblastoma multiforme: 75 mg/m^2 PO QD for 42 days followed by maintenance therapy for 6 cycles with cycle 1 including temozolomide 150 mg/m^2 PO QD for 5 days followed by 23 days without treatment and cycles 2-6 consisting of temozolomide 200 mg/m^2 PO QD for the first 5 days of each cycle Anaplastic astrocytoma: 150 mg/m^2 PO QD for 5 days of each 28-day treatment cycle	
Doxorubicin, bleomycin, vinblastine, dacarbazine (ABVD)	Hodgkin's Lymphoma Varies per protocol and patient tolerance	Varies
Doxorubicin, vinblastine, mechlorethamine, etoposide, vincristine, bleomycin, prednisone (Stanford V)	Hodgkin's Lymphoma Varies per protocol and patient tolerance	Varies
Bleomycin, etoposide, doxorubicin, cyclophosphamide, vincristine, procarbazine, prednisone (Escalated BEACOPP)	Hodgkin's Lymphoma Varies per protocol and patient tolerance	Varies
Brentuximab vedotin, doxorubicin, vinblastine, dacarbazine (Adcetris® + AVD)	Hodgkin's Lymphoma Varies per protocol and patient tolerance	Varies
Cyclophosphamide, doxorubicin, vincristine, prednisone, rituximab (CVP + Rituxan®)	Hodgkin's Lymphoma Varies per protocol and patient tolerance	Varies
Rituximab (Rituxan®)	Hodgkin's Lymphoma Varies per protocol and patient tolerance	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: 5 mg, 10 mg, 40 mg, 100 mg

VII. References

1. Gleostine Prescribing Information. Miami, FL: NextSource Biotechnology; September 2018. Available at: http://www.nextsourcepharmaceuticals.com/docs/pi/Gleostine-PI.pdf. Accessed August 10. 2023.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 10. 2023.
3. National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed August 10. 2023.
4. National Comprehensive Cancer Network. Hodgkin Lymphoma Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Accessed August 10. 2023.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 10. 2023.

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