Clinical Policy: Lomustine (Gleostine)

Reference Number: CP.PHAR.507
Effective Date: 12.01.20
Last Review Date: 11.21
Line of Business: Commercial, HIM, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

Gleostine is indicated for the treatment of patients with:

- Primary and metastatic brain tumors following appropriate surgical and/or radiotherapeutic procedures;
- Hodgkin's lymphoma whose disease has progressed following initial chemotherapy, as a component of combination 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 health plans affiliated with Centene Corporation® 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. 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).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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. 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).*

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Gleostine for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. 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*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

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 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	200 mg/m^2/day
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Varies per protocol and patient tolerance	

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 July 15, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed June 28, 2021.
3. National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed July 15, 2021.
4. National Comprehensive Cancer Network. Hodgkin Lymphoma Version 4.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf. Accessed July 13, 2021.
5. Micromedex® Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed July 15, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from previously approved policy HIM.PA.19; retire HIM.PA.19; added Commercial and Medicaid lines of business; no significant changes from previously approved policy; 4Q 2020 annual review: no significant changes; references reviewed and updated.	08.03.20	11.20
4Q 2021 annual review: for brain tumors, removed temozolomide re-direction per SDC; for Hodgkin's lymphoma, added requirement	06.28.21	11.21

Reviews, Revisions, and Approvals	Date	P&T Approval Date
for combination use per FDA label; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.		

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.