

## Clinical Policy: Lomustine (Gleostine)

Reference Number: HIM.PA.19

Effective Date: 08.28.18

Last Review Date: 11.19

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### Description

Lomustine (Gleostine<sup>®</sup>) 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;
- Patients with 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<sup>®</sup> 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. Failure of temozolomide at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;  
*\*Prior authorization may be required for temozolomide.*
4. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 130 mg/m<sup>2</sup> 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. Request meets one of the following (a or b):\*
  - a. Dose does not exceed 130 mg/m<sup>2</sup> 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): HIM.PHAR.21 for health insurance marketplace.

**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, new dose does not exceed 130 mg/m<sup>2</sup> every 6 weeks.

**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): HIM.PHAR.21 for health insurance marketplace.

**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 – HIM.PHAR.21 for health insurance marketplace 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®)	<u>Brain Tumors</u> Glioblastoma multiforme: 75 mg/m <sup>2</sup> PO QD for 42 days followed by maintenance	200 mg/m <sup>2</sup> /day

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

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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 <sup>2</sup> PO one time every 6 weeks	130 mg/m <sup>2</sup> 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; January 2016. Available at: <http://www.nextsourcepharmaceuticals.com/docs/pi/Gleostine-PI.pdf>. Accessed August 10, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: [http://www.nccn.org/professionals/drug\\_compendium](http://www.nccn.org/professionals/drug_compendium). Accessed August 10, 2019.
3. National Comprehensive Cancer Network. Central Nervous System Cancers Version 1.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/cns.pdf](https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf). Accessed August 10, 2019.
4. National Comprehensive Cancer Network. Hodgkin Lymphoma Version 2.2019. Available at: [https://www.nccn.org/professionals/physician\\_gls/pdf/hodgkins.pdf](https://www.nccn.org/professionals/physician_gls/pdf/hodgkins.pdf). Accessed August 10, 2019.
5. Micromedex<sup>®</sup> Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed August 10, 2019.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.22.18	10.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	08.10.19	11.19

**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

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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.

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**Note:**

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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