LOMUSTINE

Generic	Brand	HICL	GCN	Exception/Other
LOMUSTINE	GLEOSTINE	03900		

GUIDELINES FOR USE

1. Is the request for treatment of Hodgkin's Lymphoma?

   If yes, **approve for 12 months by HICL.**
   If no, continue to #2.

2. Is the request for treatment of primary and metastatic brain tumors and the patient has previously received appropriate surgical and/or radiotherapeutic procedures?

   If yes, continue to #3
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Will the patient be using this medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine) **OR** has the patient had a previous trial of IV carmustine?

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

DENIAL TEXT: The guideline named **LOMUSTINE (Gleostine)** requires a diagnosis of Hodgkin's Lymphoma or that the request is being used for the treatment of primary and metastatic brain tumors in patients who previously received appropriate surgical and/or radiotherapeutic procedures. Patients with primary and metastatic brain tumors must be using the medication as a part of the PCV regimen (procarbazine, lomustine, and vincristine) or had a previous trial of IV carmustine.

RATIONALE

To promote appropriate utilization of Gleostine based on its FDA approved indication and NCCN guidelines.

FDA APPROVED INDICATIONS

Gleostine is an alkylating drug 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.

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LOMUSTINE

FDA APPROVED INDICATIONS (CONTINUED)

DOSING

The recommended dose of Gleostine in adult and pediatric patients is 130 mg/m^2 taken as a single oral dose every 6 weeks.

- Round doses to the nearest 5 mg.
- Give as a single oral dose and do not repeat for at least 6 weeks.
- Reduce dose to 100 mg/m^2 every 6 weeks in patients with compromised bone marrow function. Also reduce dose accordingly when using with other myelosuppressive drugs.

Perform weekly complete blood counts and withhold each subsequent dose for more than 6 weeks if needed until platelet counts recover to 100,000/mm^3 or greater and leukocytes recover to 4000/mm^3 or greater. Modify each dose of Gleostine according to the hematologic response of the preceding dose as described in the table below.

Nadir After Prior Dose		Dose Adjustment
Leukocytes (/mm^3)	Platelets	
≥ 4,000	≥ 100,000	None
3,000-3,999	75,000-99,999	None
2,000-2,999	25,000-74,999	Reduce dose by 30%
<2,000	< 25,000	Reduce dose by 50%

REFERENCES

- Gleostine [Prescribing Information]. NextSource Biotechnology, LLC: Miami, FL; January 2016.
- National Comprehensive Cancer Network. NCCN Guidelines: Central Nervous System Cancers Version 1. 2017. Updated September 25, 2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/all.pdf. Accessed February 16, 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/18
Created: 02/18
Client Approval: 03/18
P&T Approval: 01/18