Gleostine (Iomustine)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications	
Gleostine (lomustine)	

APPROVAL CRITERIA

Requests for Gleostine (lomustine) may be approved if the following criteria are met:

- I. Individual has a diagnosis of brain tumors, including malignant glioma and brain metastases: **AND**
- II. Individual has already received surgical and/or radiotherapeutic procedures;

OR

III. Individual has relapsed or refractory Hodgkin's lymphoma;

OR

- IV. Individual has a diagnosis of one of the following central nervous system cancers:
 - A. Adult intracranial and spinal ependymoma (excluding subependymoma) (NCCN 2A): **OR**
 - B. Adult glioma (including circumscribed glioma, glioblastoma, gliosarcoma, high-grade glioma, astrocytoma, or oligodendroglioma) (NCCN 2A); **OR**
 - C. Adult medulloblastoma (NCCN 2A); OR
 - D. Pediatric diffuse High-Grade gliomas or pediatric diffuse midline glioma (NCCN 2A).

Note:

Gleostine (lomustine) has a black box warning for delayed myelosuppression and risk of overdose. Myelosuppression is delayed, dose-related, and cumulative; occurring 4 to 6 weeks after drug administration and persisting for 1 to 2 weeks. Thrombocytopenia is generally more severe than leukopenia. Courses of Gleostine (lomustine) should not be given more frequently than every six weeks at the recommended dosage; and blood counts should be monitored for at least six weeks after a dose. Prescribe, dispense, and administer only enough Gleostine capsules for one dose as fatal toxicity occurs with overdosage. Only one dose is taken every 6 weeks.

Key References:

- 1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. URL: http://www.clinicalpharmacology.com. Updated periodically.
- 2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 14, 2023.
- 3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- 4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
- 5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on October 14, 2023.
- 6. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
 - a. Pediatric Central Nervous System Cancers. V2.2023. Revised October 31, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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