

Applicable Drugs: Gleostine (lomustine)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 5/21/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of one of the following FDA-approved diagnoses A or B AND must meet criteria listed under applicable diagnosis:
FDA-Approved Indication(s)
 - A. Primary or metastatic brain tumor
 1. Documentation of use following appropriate surgical and/or radiotherapeutic procedures.
 - B. Hodgkin's lymphoma
 1. Documentation of disease progression with initial chemotherapy.
 2. Documentation that lomustine will be used in combination with other chemotherapies.
- II. Minimum age requirement: 1 year old and older
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity is limited to the number of capsules needed to fill a single dose of up to 130 mg/m² (rounded to the nearest 10 mg) once every 6 weeks.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

1. Gleostine. Prescribing information. NextSource Biotechnology; 2024. Accessed June 12, 2025. <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=7f77526b-4c40-409c-82ea-d0f934d89cc2&type=display>
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Central Nervous System Cancers. Version 1.2026. Updated April 24, 2026. Accessed June 1, 2026.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.