

Generic Name: Lomustine

Therapeutic Class or Brand Name: Gleostine®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/1/2013

Date Last Reviewed / Revised: 9/22/2023

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:
 - A. Primary or metastatic brain tumors
 1. Documentation of appropriate surgical and/or radiotherapeutic procedures.
 2. Dose does not exceed 130mg/m² every 6 weeks.
 - B. Hodgkin's lymphoma
 1. Documentation of relapse or treatment failure to initial chemotherapy.
 2. Documentation that Gleostine® will be used in combination with other chemotherapies.
 3. Dose does not exceed 130mg/m² every 6 weeks.
- II. Minimum age requirement: 18 years
- 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 clinical practice guidelines.
- 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

- Pregnancy

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 that the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Gleostine®. Prescribing information. NextSource Biotechnology; 2018. Accessed August 21, 2023. <https://www.nextsourcepharma.com/docs/pi/Gleostine-PI.pdf>.
2. National Comprehensive Cancer Network (NCCN). Central Nervous System Cancers. Version 1.2023. Updated March 24, 2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed September 22, 2023.

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.