

Generic Name: Lomustine**Preferred:** N/A**Therapeutic Class or Brand Name:** Gleostine®**Non-preferred:** N/A**Applicable Drugs (if Therapeutic Class):** N/A**Date of Origin:** 2/1/2013**GPI Code:** 2110202000**Date Last Reviewed / Revised:** 1/22/2020

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of one of the following conditions A or B AND must meet criteria listed under applicable diagnosis:
 - A. Brain tumor and criterion 1 is met:
 1. Patient has already received appropriate surgical and/or radiotherapeutic procedures.
 - B. Hodgkin's lymphoma and criteria 1 AND 2 are met:
 1. Patient relapsed or failed to respond to primary therapy.
 2. Documentation that Gleostine® will be used in combination with other chemotherapies.
- II. The prescribing physician is an oncologist or a hematologist.

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 5 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. National Comprehensive Cancer Network (NCCN). Central Nervous System Cancers. Version 3.2019. Updated October 18, 2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf
2. Medi-Span®.
3. Gleostine [Package Insert]. Miami, FL: NextSource Biotechnology. September 2018. Available at: <http://www.nextsourcebiotechnology.com/docs/pi/Gleostine-PI.pdf> .

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/22/2020	1. Added " https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf " under References.
10/19/2018	1. Added: registered trademark symbol to reference #1 Medi-Span.
12/5/2017	1. Policy reviewed: no changes made.
9/24/2016	<ol style="list-style-type: none"> 1. Changed Brand Name from "Gleostine™" to "Gleostine®". 2. Changed "I. B. Hodgkin's disease and criterion 1 is met: 1. Patient relapsed or failed to respond to primary therapy" to "I. B. Hodgkin's lymphoma and criteria 1 AND 2 are met: 1. Patient relapsed or failed to respond to primary therapy; 2. Documentation that Gleostine® will be used in combination with other chemotherapies" under Prior Authorization Criteria. 3. Changed "... (rounded to the nearest 10mg) ..." to "... (rounded to the nearest 5 mg) ..." under Quantity/Days Supply Restrictions. 4. Removed "http://www.keystonevipchoice.com/pdf/member/eng/2013-prior-authorization-criteria.pdf", "http://packageinserts.bms.com/pi/pi_ceenu.pdf", and "http://www.nextsourcebiotechnology.com/docs/pi/LomustineCCNU-PI.pdf" from References (links no longer valid). 5. Updated "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7f77526b-4c40-409c-82ea-d0f934d89cc2" to "http://www.nextsourcebiotechnology.com/docs/pi/Gleostine-PI.pdf" under References.
3/24/2015	<ol style="list-style-type: none"> 1. Changed policy name from "CeeNU" to "Gleostine" (CeeNU® brand has been discontinued and Gleostine is the new brand name for lomustine). 2. Changed "CeeNU®" to "Gleostine™" following Therapeutic Class or Brand Name. 3. Removed "http://www.fdhc.state.fl.us/medicaid/Prescribed_Drug/drug_criteria_pdf/Oral_Oncology_Criteria.pdf" from References (link no longer valid). 4. Added "http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=7f77526b-4c40-409c-82ea-d0f934d89cc2" and "http://www.nextsourcebiotechnology.com/docs/pi/LomustineCCNU-PI.pdf" under References.
11/27/2013	<ol style="list-style-type: none"> 1. Adapted policy to new format. 2. Added GPI Code. 3. Changed "Prescriber must be an oncologist" to "The prescribing physician is an oncologist or a hematologist" under Prior Authorization Criteria. 4. Changed Quantity/Days Supply Restrictions from "6 capsules per 30 days, and 1 fill per 6 weeks (dose is limited to 130 mg/m² (rounded to the nearest 10 mg) as a single oral dose every 6 weeks)" to "Quantity is limited to the number of capsules needed to fill a single dose of up to 130 mg/m² (rounded to the nearest 10mg) once every 6 weeks". 5. Updated references to include Medi-Span.

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.