MEDICATION POLICY

Generic Name: Lomustine

Therapeutic Class or Brand Name: Gleostine®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/24/16

GPI Code: 2110202000

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/m^2 (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.

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Appendix:

N/A

References:

1. Medi-Span.
2. http://www.nextsourcebiotechnology.com/docs/pi/Gleostine-PI.pdf.

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Historical Tracking Of Changes Made To Policy	
9/24/2016	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and** "http://www.nextsourcebiotechnology.com/docs/pi/LomustineCCNU-PI.pdf" **from References** (links no longer valid). 5.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	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_creteria_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	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/m^2 (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/m^2 (rounded to the nearest 10mg) once every 6 weeks". 5. **Updated references** to include Medi-Span.