

**POLICY:** Oncology – Carmustine Injection (BICNU® – Heritage Pharmaceuticals, generics)

**DATE REVIEWED:** 12/18/2019

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### OVERVIEW

Carmustine injection, a nitrosourea, is approved for the following uses as a palliative agent as a single agent or in established combination therapy in the following conditions:<sup>1</sup>

- Brain tumors, including glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors; AND
- Multiple myeloma, in combination with prednisone; AND
- Hodgkin's lymphoma, in relapsed or refractory disease in combination with other approved drugs; AND
- Non-Hodgkin's lymphoma, in relapsed or refractory disease in combination with other approved drugs.

### Guidelines

The National Comprehensive Cancer Network (NCCN) clinical practice guidelines on Central Nervous System Cancers (version 3.2019 – October 18, 2019) supports use of carmustine injection for certain adults with recurrent or progressive low-grade glioma/pilocytic and infiltrative supratentorial astrocytoma/oligodendroglioma, recurrent treatment of anaplastic glioma, glioblastoma, adult intracranial and spinal ependymoma (excluding subependymoma).<sup>2,3</sup> Carmustine injection is also part of a Preferred regimen (in combination with thiotepa) as consolidation therapy with stem cell rescue in patients with primary CNS lymphoma.<sup>2,4</sup>

The NCCN clinical practice guidelines on Hodgkin Lymphoma (version 2.2019 – July 15, 2019) recommend carmustine as part of a chemotherapy regimen (e.g., MiniBEAM [carmustine/cytarabine/etoposide/melphalan]) for relapsed or refractory disease.<sup>5</sup>

The NCCN clinical practice guidelines on Multiple Myeloma (version 2.2020 – October 9, 2019) and B-Cell Lymphomas (version 5.2019 – September 23, 2019) do not provide recommendations on the use of carmustine for the treatment of multiple myeloma or non-Hodgkin's lymphoma.<sup>6,7</sup>

### POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of carmustine products. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the specialized skills required for evaluation and diagnosis of patients treated with carmustine products as well as the monitoring required for adverse events and long-term efficacy, approval requires carmustine products to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

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## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of carmustine injection (BICNU, generics) is recommended in those who meet the following criteria:

### FDA-Approved Indications

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**1. Central Nervous System Tumor** (Note: Includes Adult Low-Grade Infiltrative Supratentorial Astrocytoma/Oligodendroglioma, Anaplastic Gliomas, Glioblastoma, Adult Intracranial and Spinal Ependymoma, Primary Central Nervous System Lymphoma). Approve for 1 year if the patient meets the following criteria (A and B):

A) The patient meets ONE of the following (i or ii):

- i. The patient has recurrent or progressive disease; OR
- ii. The agent is being used in a regimen with stem cell rescue.

Note: For example, as consolidation therapy in combination with thiotepa with stem cell rescue; AND

B) The agent is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A or B):

A) Each individual dose must not exceed 200 mg/m<sup>2</sup> administered intravenously no more frequently than once every 6 weeks; OR

B) Each individual dose must not exceed 100 mg/m<sup>2</sup> administered intravenously no more frequently than twice every 6 weeks.<sup>1</sup>

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**2. Hodgkin Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B, C, and D):

A) The patient is ≥ 18 years of age; AND

B) The patient has relapsed or refractory disease; AND

C) The agent is being used as part of a chemotherapy regimen.

Note: For example, as a component of MiniBEAM (carmustine/cytarabine/etoposide/melphalan); AND

D) The agent is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A or B):

A) Each individual dose must not exceed 200 mg/m<sup>2</sup> administered intravenously no more frequently than once every 6 weeks; OR

B) Each individual dose must not exceed 100 mg/m<sup>2</sup> administered intravenously no more frequently than twice every 6 weeks.<sup>1</sup>

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**3. Non-Hodgkin's Lymphoma.** Approve for 1 year if the patient meets the following criteria (A, B, and C):

A) The patient has relapsed or refractory disease; AND

B) The agent is being used as part of a chemotherapy regimen; AND

C) The agent is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A or B):

- A) Each individual dose must not exceed 200 mg/m<sup>2</sup> administered intravenously no more frequently than once every 6 weeks; OR
- B) Each individual dose must not exceed 100 mg/m<sup>2</sup> administered intravenously no more frequently than twice every 6 weeks.<sup>1</sup>

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**4. Multiple Myeloma.** Approve for 1 year if the patient meets the following criteria (A and B):

- A) The agent is being used with prednisone: AND
- B) The agent is prescribed by or in consultation with an oncologist.

**Dosing.** Approve ONE of the following dosing regimens (A or B):

- A) Each individual dose must not exceed 200 mg/m<sup>2</sup> administered intravenously no more frequently than once every 6 weeks; OR
- B) Each individual dose must not exceed 100 mg/m<sup>2</sup> administered intravenously no more frequently than twice every 6 weeks.<sup>1</sup>

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**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Carmustine has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions.

- 1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**

- 1. BICNU [prescribing information]. East Brunswick, NJ: Heritage Pharmaceuticals; September 2018.
- 2. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (Version 3.2019 – October 18, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 21, 2019.
- 3. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 21, 2019. Search term: carmustine.
- 4. The NCCN Drugs and Biologics Compendium. © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 21, 2019. Search term: carmustine implant.
- 5. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2019 – July 15, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 21, 2019.
- 6. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (Version 2.2020 – October 9, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 21, 2019.
- 7. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (Version 5.2019 – September 23, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on October 21, 2019.

**HISTORY**

Type of Revision	Summary of Changes	Date Reviewed
New Policy	--	12/18/2019