PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Injectable) – Carmustine Products Prior Authorization Policy
- Carmustine intravenous infusion (BICNU® – Avet, generics)

REVIEW DATE: 12/21/2022

OVERVIEW

Carmustine intravenous infusion, 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:[1]

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

Guidelines

Carmustine is addressed in the following National Comprehensive Cancer Network (NCCN) guidelines:

- **Central nervous system (CNS) cancers** (version 2.2022 – September 29, 2022) clinical practice guidelines support the use of carmustine injection for certain adults with recurrent or progressive low-grade glioma/pilocytic and infiltrative supratentorial astrocytoma/oligodendroglioma, and recurrent anaplastic glioma, glioblastoma, adult intracranial and spinal ependymoma (excluding subependymoma).[2,3] 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. The **pediatric CNS** (version 2.2023 – October 31, 2022) recommend carmustine for the palliative treatment of patients with diffuse high-grade gliomas.[3,8]
- **Hematopoietic Cell Transplantation** (version 2.2022 – September 28, 2022) clinical practice guidelines recommend carmustine as part of a conditioning regimen prior to autologous hematopoietic cell transplantation (category 2A) in patients with non-Hodgkin lymphoma, Hodgkin lymphoma, or primary CNS lymphoma.[3,7]
- **Hodgkin lymphoma** (version 2.2023 – November 8, 2022) clinical practice guidelines recommend carmustine as part of a chemotherapy regimen (e.g., MiniBEAM [carmustine/cytarabine/etoposide/melphalan]) for disease that is refractory to at least three prior lines of therapy.[3,4]

The NCCN clinical practice guidelines on **multiple myeloma** (version 3.2022 – December 8, 2022) and **B-cell lymphomas** (version 5.2022 – July 12, 2022) do not provide recommendations on the use of carmustine for the treatment of these respective indications.[5,6]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of carmustine products. 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Central Nervous System Tumor.** Approve for 1 year if the patient meets ONE of the following criteria (A or B):
   Note: Includes adult low-grade infiltrative supratentorial astrocytoma/oligodendroglioma, anaplastic gliomas, glioblastoma, adult intracranial and spinal ependymoma, primary central nervous system lymphoma, pediatric diffuse high-grade gliomas.
   - **A)** Patient is ≥ 18 years of age: Approve if the patient meets BOTH of the following (i and ii):
     - **i.** Patient meets ONE of the following (a, b, or c):
       - **a)** Patient has recurrent or progressive disease; OR
       - **b)** The medication is being used in a regimen with stem cell rescue; OR
         Note: For example, as consolidation therapy in combination with thiotepa with stem cell rescue.
       - **c)** The medication is used in place of lomustine in any PCV (procarbazine, lomustine, and vincristine) regimen; AND
     - **ii.** The medication is prescribed by or in consultation with an oncologist.
   - **B)** Patient is < 18 years of age: Approve if the patient meets ALL of the following (i, ii, and iii):
     - **i.** Patient has diffuse high-grade glioma; AND
     - **ii.** The medication is used for palliative treatment; AND
     - **iii.** The medication is prescribed by or in consultation with an oncologist.

2. **Hodgkin Lymphoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** The medication is being used as part of a chemotherapy regimen; AND
     Note: For example, as a component of MiniBEAM (carmustine/cytarabine/etoposide/melphalan).
   - **D)** The medication is prescribed by or in consultation with an oncologist.

3. **Multiple Myeloma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is being used with prednisone; AND
   - **C)** The medication is prescribed by or in consultation with an oncologist.

4. **Non-Hodgkin Lymphoma.** Approve for 1 year if the patient meets ALL of the following criteria (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has relapsed or refractory disease; AND
   - **C)** The medication is being used as part of a chemotherapy regimen; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist.

Other Uses with Supportive Evidence

5. **Hematopoietic Cell Transplantation.** Approve for 1 month if the patient meets ALL of the following criteria (A, B, and C):
   A) Patient is undergoing an autologous transplant; AND
   B) The medication is being used as part of a conditioning regimen, given prior to transplantation; AND
   C) The medication is prescribed by or in consultation with an oncologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of carmustine intravenous infusion is not recommended in the following situations:

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: Avet Pharmaceuticals; November 2021.
2. The NCCN Central Nervous System Clinical Practice Guidelines in Oncology (version 2.2022 – September 29, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022.
3. The NCCN Drugs and Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022. Search term: carmustine.
4. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 2.2023 – November 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022.
5. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 3.2023 – December 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022.
6. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 5.2022 – July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022.
7. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 2.2022 – September 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022.
8. The NCCN Pediatric Central Nervous System Clinical Practice Guidelines in Oncology (version 2.2023 – October 31, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 15, 2022.