CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Carmustine Products Utilization Management Medical Policy
- Carmustine intravenous infusion (BICNU® – Avet, generics)

REVIEW DATE: 01/29/2025

OVERVIEW

Carmustine intravenous infusion, a nitrosourea, is approved as palliative therapy 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 3.2024 – September 30, 2024) 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 2.2025 – January 17, 2025) recommend carmustine for the palliative treatment of patients with diffuse high-grade gliomas.[3,9]
- **Hematopoietic Cell Transplantation** (version 2.2024 – August 30, 2024) 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]

The NCCN clinical practice guidelines on **Hodgkin Lymphoma** (version 1.2025 – December 24, 2024), **Multiple Myeloma** (version 1.2025 – September 17 2024) and **B-Cell Lymphomas** (version 1.2025 – December 20, 2024) do not provide recommendations on the use of carmustine for the treatment of these respective indications.[4-6]

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 indications. 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

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1. Central Nervous System Tumor. Approve for 1 year if the patient meets ONE of the following (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; OR

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.

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

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

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

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2. Hodgkin Lymphoma. Approve for 1 year if the patient meets ALL of the following (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.

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

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

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

3. Multiple Myeloma. Approve for 1 year if the patient meets ALL of the following (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.

Dosing. Approve ONE of the following dosing regimens (A or B):
- **A)** Each individual dose must not exceed 200 mg/m^2 administered intravenously no more frequently than once every 6 weeks; OR
- **B)** Each individual dose must not exceed 100 mg/m^2 administered intravenously no more frequently than twice every 6 weeks.

4. Non-Hodgkin Lymphoma. Approve for 1 year if the patient meets ALL of the following (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.

Dosing. Approve ONE of the following dosing regimens (A or B):
- **A)** Each individual dose must not exceed 200 mg/m^2 administered intravenously no more frequently than once every 6 weeks; OR
- **B)** Each individual dose must not exceed 100 mg/m^2 administered intravenously no more frequently than twice every 6 weeks.

Other Uses with Supportive Evidence

5. Hematopoietic Cell Transplantation. Approve for 1 month if the patient meets ALL of the following (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.

Dosing. Approve up to 400 mg/m^2 administered intravenously once prior to autologous hematopoietic cell transplantation.

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 3.2024 – September 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.

3. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025. Search term: carmustine.
4. The NCCN Hodgkin Lymphoma Clinical Practice Guidelines in Oncology (version 1.2025 – December 24, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.
5. The NCCN Multiple Myeloma Clinical Practice Guidelines in Oncology (version 1.2025 – September 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.
6. The NCCN B-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 1.2025 – December 20, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.
7. The NCCN Hematopoietic Cell Transplantation (HCT) Clinical Practice Guidelines in Oncology (version 2.2024 – August 30, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.
8. Ferreri AJM, Illerhaus G. The role of autologous stem cell transplantation in primary central nervous system lymphoma. *Blood*. 2016;127:1642-1649.
9. The NCCN Pediatric Central Nervous System Clinical Practice Guidelines in Oncology (version 2.2025 – January 17, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 21, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	01/10/2024
Annual Revision	No criteria changes.	01/29/2025