Reference number(s)
4808-A

Standard Medicare Part B Management Carmustine

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
carmustine (brand unavailable)	carmustine

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met, and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Carmustine for injection is indicated as palliative therapy as a single agent or in established combination therapy in the following:

- Brain tumors glioblastoma, brainstem glioma, medulloblastoma, astrocytoma, ependymoma, and metastatic brain tumors
- Multiple myeloma-in combination with prednisone
- Relapsed or refractory Hodgkin's lymphoma in combination with other approved drugs
- Relapsed or refractory non-Hodgkin's lymphomas in combination with other approved drugs

Compendial Uses[2-3]

- Central Nervous System Cancers: Adult glioma, pediatric diffuse high-grade glioma, anaplastic gliomas, glioblastoma, adult intracranial and spinal ependymoma (excluding subependymoma), primary CNS lymphoma
- Classic Hodgkin Lymphoma

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- Mycosis Fungoides/Sezary Syndrome
- Smoldering adult T-cell leukemia/lymphoma
- Waldenstrom macroglobulinemia
- Gastric carcinoma
- Advanced melanoma
- Hematopoietic Cell Transplantation

All other indications will be assessed on an individual basis. Submissions for indications other than those listed in this criteria should be accompanied by supporting evidence from Medicare approved compendia.

Coverage Criteria

Central Nervous System Cancers[1,2]

Authorization of 12 months may be granted for treatment of central nervous system cancers including the following: glioblastoma, adult glioma, brainstem glioma, anaplastic gliomas, pediatric diffuse high-grade glioma, medulloblastoma, astrocytoma, ependymoma, primary CNS lymphoma, and metastatic brain tumors.

Multiple Myeloma[1]

Authorization of 12 months may be granted for treatment of multiple myeloma when the requested drug is used in combination with prednisone.

Lymphoma[1-3]

Authorization of 12 months may be granted for treatment of relapsed, refractory, or heavily pretreated lymphoma.

Mycosis Fungoides/Sezary Syndrome[2,3]

Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

Adult T-Cell Leukemia/Lymphoma[2]

Authorization of 12 months may be granted for treatment of smoldering adult T-cell leukemia/lymphoma.

Waldenstrom Macroglobulinemia[3]

Authorization of 12 months may be granted for treatment of Waldenstrom macroglobulinemia.

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Gastric Carcinoma[3]

Authorization of 12 months may be granted for palliative therapy as a single agent or in combination therapy for gastric carcinoma.

Melanoma[3]

Authorization of 12 months may be granted for treatment of advanced malignant or advanced metastatic melanoma.

Hematopoietic Cell Transplantation[2]

Authorization of 12 months may be granted for hemopoietic cell transplantation conditioning when any of the following criteria are met:

- The requested drug is being used as part of BEAM (carmustine, etoposide, cytarabine and melphalan) regimen.
- The requested drug is being used as part of BEAC (carmustine, etoposide, cytarabine and cyclophosphamide) regimen.
- The requested drug is being used in combination with thiotepa for autologous transplant in Non-Hodgkin Lymphoma (NHL) with or without CNS disease, Hodgkin Lymphoma, or Primary Central Nervous System Lymphoma.

Continuation of Therapy

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested drug.

Authorization for 12 months may be granted when all of the following criteria are met:

- The member is currently receiving therapy with the requested drug
- BiCNU is being used to treat an indication in the coverage criteria section
- The member is receiving benefit from therapy. Benefit is defined as:
    - No evidence of unacceptable toxicity while on the current regimen and
    - No evidence of disease progression while on the current regimen.

Summary of Evidence

The contents of this policy were created after examining the following resources:

- The prescribing information for carmustine.
- The available compendium

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  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
  - Micromedex DrugDex
  - American Hospital Formulary Service- Drug Information (AHFS-DI)
  - Lexi-Drugs
  - Clinical Pharmacology
- NCCN Guideline: Pediatric central nervous system cancers
- NCCN Guideline: Hodgkin lymphoma
- NCCN Guideline: Hematopoietic cell transplantation
- NCCN Guideline: Central nervous system cancers
- NCCN Guideline: Primary cutaneous lymphomas
- NCCN Guideline: T-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for BiCNU are covered in addition to the following:

- Central Nervous System Cancers: Adult glioma, pediatric diffuse high-grade glioma, anaplastic gliomas, glioblastoma, adult intracranial and spinal ependymoma (excluding subependymoma), primary CNS lymphoma
- Classic Hodgkin Lymphoma
- Mycosis Fungoides/Sezary Syndrome
- Smoldering adult T-cell leukemia/lymphoma
- Waldenstrom macroglobulinemia
- Gastric carcinoma
- Advanced melanoma
- Hematopoietic Cell Transplantation

Explanation of Rationale

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using carmustine to treat central nervous system cancers, lymphoma, mycosis fungoides/Sezary syndrome, hematopoietic cell transplantation, and adult T-cell leukemia/lymphoma can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using carmustine to treat lymphoma, Waldenstrom macroglobulinemia, gastric carcinoma, and melanoma can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is

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supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

References

1. Carmustine [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; June 2023.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 6, 2025.
3. IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com/ (cited: November 6, 2025).

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