Reference number(s)
4808-A

STANDARD MEDICARE PART B MANAGEMENT

BiCNU (carmustine)

POLICY

I. 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.

A. FDA-Approved Indications

BiCNU is indicated as palliative therapy as a single agent or in established combination therapy with other approved chemotherapeutic agents in the following:

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

B. Compendial Uses

1. Central Nervous System Cancers: Adult low-grade glioma, anaplastic gliomas, glioblastoma, adult intracranial and spinal ependymoma (excluding subependymoma), primary CNS lymphoma
2. Classic Hodgkin Lymphoma
3. Bone marrow transplant, preparative regimens
4. Mycosis Fungoides/Sezary Syndrome
5. Chronic/smoldering adult T-cell leukemia/lymphoma
6. Waldenstrom macroglobulinemia
7. Gastric carcinoma
8. Advanced melanoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Central Nervous System Cancers

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

B. Multiple Myeloma

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

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

D. Mycosis Fungoides/Sezary Syndrome
Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

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

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

G. Gastric Carcinoma
Authorization of 12 months may be granted for treatment of gastric carcinoma.

H. Melanoma
Authorization of 12 months may be granted for treatment of advanced melanoma.

III. CONTINUATION OF THERAPY

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

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with BiCNU
B. BiCNU is being used to treat an indication enumerated in Section II
C. The member is receiving benefit from therapy. Benefit is defined as:
   1. No evidence of unacceptable toxicity while on the current regimen and
   2. No evidence of disease progression while on the current regimen.

IV. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for BiCNU.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Pediatric central nervous system cancers
4. NCCN Guideline: Hodgkin lymphoma
5. NCCN Guideline: Hematopoietic cell transplantation

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6. NCCN Guideline: Central nervous system cancers
7. NCCN Guideline: Primary cutaneous lymphomas
8. 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:

1. Central Nervous System Cancers: Adult low-grade glioma, anaplastic gliomas, glioblastoma, adult intracranial and spinal ependymoma (excluding subependymoma), primary CNS lymphoma
2. Classic Hodgkin Lymphoma
3. Bone marrow transplant, preparative regimens
4. Mycosis Fungoides/Sezary Syndrome
5. Chronic/smoldering adult T-cell leukemia/lymphoma
6. Waldenstrom macroglobulinemia
7. Gastric carcinoma
8. Advanced melanoma

V. EXPLANATION OF RATIONALE

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

Support for using BiCNU to treat central nervous system cancers, lymphoma, mycosis fungoides/Sezary syndrome, 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 BiCNU 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 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).

VI. REFERENCES

1. BiCNU [package insert]. East Brunswick, NJ: Heritage Pharmaceuticals Inc.; November 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 1, 2022.
3. BiCNU. Micromedex Solutions. Greenwood Village, CO: Truven Health Analytics. http://micromedex.com/. Accessed November 1, 2022.

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