

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Temozolomide Prior Authorization Policy
- Temozolomide capsules (Temodar® – Merck & Co, generic)

REVIEW DATE: 08/12/2020

OVERVIEW

Temozolomide, an alkylating agent, is indicated in adults for the following uses:¹

- **Anaplastic astrocytoma**, that is refractory, in patients who have experienced disease progression on a drug regimen containing nitrosourea (i.e., BiCNU® [carmustine {BCNU} for injection] or lomustine [CCNU] capsules) and Matulane® (procarbazine capsules).
- **Glioblastoma**, newly diagnosed, concomitantly used with radiotherapy and then as maintenance therapy.

Guidelines

- **Anaplastic Astrocytoma, Glioblastoma, and Other Central Nervous System (CNS) Tumors:** The National Comprehensive Cancer Network (NCCN) CNS cancers clinical practice guidelines (version 2.2020 – April 30, 2020) note temozolomide as a treatment option for the treatment of glioblastoma and anaplastic astrocytoma.² Temozolomide is listed for use as monotherapy or as adjuvant therapy (i.e., to be used concurrently with radiation or other chemotherapeutic agents). The guidelines note temozolomide as an option for a myriad of CNS cancers, including anaplastic gliomas (includes mixed anaplastic oligoastrocytoma, anaplastic oligodendroglioma, and other rare anaplastic glioma); intracranial or spinal ependymoma; gliosarcoma; primary CNS lymphoma; low-grade glioma/pilocytic and infiltrative supratentorial astrocytoma/oligodendroglioma; medulloblastoma (as recurrence therapy in patients who have tried other chemotherapeutic agents); and brain metastases from solid tumors (in patients for whom radiation therapy is not an option and who have tried other chemotherapeutic drugs that penetrate the CNS).
- **Ewing's sarcoma or mesenchymal chondrosarcoma:** The NCCN bone cancer guidelines (version 1.2020 – August 12, 2019) note temozolomide as a treatment option in patients with relapsed, refractory, or metastatic disease.³
- **Melanoma:** The NCCN cutaneous melanoma guidelines (version 3.2020 – May 18, 2020) note temozolomide as a treatment option in patients with metastatic melanoma.⁴
- **Neuroendocrine tumors:** The NCCN guidelines (version 2.2020 – July 24, 2020) recommends use of temozolomide for neuroendocrine tumors of the gastrointestinal tract, lung or thymus (carcinoid tumors), pancreas, pheochromocytomas/paragangliomas, and poorly differentiated carcinomas/large or small cell.⁵
- **Mycosis fungoides (MF)/Sezary Syndrome:** The NCCN primary cutaneous lymphomas guidelines (version 2.2020 – April 10, 2020) note temozolomide as a treatment option for this condition in patients who have tried other chemotherapeutic agents; and for primary cutaneous anaplastic large cell lymphoma with multifocal lesions or regional nodes (in patients with CNS involvement).^{6,7}
- **Small cell lung cancer:** The NCCN small cell lung cancer guidelines (version 1.2021 – August 4, 2020) note temozolomide as one of the subsequent therapy options for patients with relapsed disease ≤ 6 months.⁸ It may be useful in patients with brain metastases.
- **Soft tissue sarcomas:** The NCCN soft tissue sarcoma guidelines (version 2.2020 – May 28, 2020) note temozolomide as a treatment option for angiosarcoma, rhabdomyosarcoma, solitary fibrous

tumor; soft tissue sarcomas (in patients with advanced, unresectable, or metastatic disease who have tried other chemotherapeutic agents).⁹

- **Uterine sarcoma:** The NCCN uterine neoplasms guidelines (version 2.2020 – July 24, 2020) note temozolomide as a treatment option for patients with metastatic, recurrent, or medically inoperable uterine sarcoma.¹⁰
- **Uveal melanoma:** The NCCN uveal melanoma guidelines (version 1.2020 – May 21, 2020) note temozolomide as a treatment option for patients with metastatic or unresectable uveal melanoma.¹¹

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of temozolomide capsules. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of temozolomide capsules is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Anaplastic Astrocytoma.** Approve for 3 years.
2. **Glioblastoma multiforme (GBM, Glioblastoma, Grade IV Astrocytoma).** Approve for 3 years.

Other Uses with Supportive Evidence

3. **Anaplastic Gliomas (Includes Mixed Anaplastic Oligoastrocytoma, Anaplastic Oligodendroglioma, and Other Rare Anaplastic Gliomas).** Approve for 3 years.
4. **Angiosarcoma.** Approve for 3 years.
5. **Brain Metastases from Solid Tumors.** Approve for 3 years if the patient meets the following criteria (A and B):
 - A) Radiation therapy is not an option; AND
 - B) At least one chemotherapy drug that penetrates the central nervous system has already been tried.

Note: Examples of chemotherapy are cyclophosphamide/methotrexate/fluorouracil for breast cancer, carboplatin and etoposide for non-small cell lung cancer.
6. **Ependymoma, Intracranial or Spinal.** Approve for 3 years.
7. **Ewing's Sarcoma or Mesenchymal Chondrosarcoma.** Approve for 3 years in patients with relapsed, refractory or metastatic disease.
8. **Gliosarcoma.** Approve for 3 years.
9. **Low-Grade (WHO Grade I or II) Glioma/ Pilocytic and Infiltrative Supratentorial Astrocytoma/Oligodendroglioma in Adults.** Approve for 3 years.

10. **Medulloblastoma.** Approve for 3 years for recurrence therapy in patients who have received prior chemotherapy.
11. **Melanoma.** Approve for 3 years if the patient has metastatic melanoma.
12. **Mycosis Fungoides/Sézary Syndrome.** Approve for 3 years in patients who have received one prior therapy.
13. **Neuroendocrine Tumors of the Gastrointestinal Tract, Lung or Thymus (Carcinoid Tumors).** Approve for 3 years.
14. **Neuroendocrine Tumors of the Pancreas (Islet Cell Tumors), Pancreatic Neuroendocrine Tumors.** Approve for 3 years.
15. **Neuroendocrine Carcinoma – Poorly Differentiated, Large or Small Cell (Other than Lung), Unknown Primary.** Approve for 3 years.
16. **Pheochromocytoma or Paragangliomas.** Approve for 3 years in patients with metastases.
17. **Primary Central Nervous System Lymphoma.** Approve for 3 years.
18. **Primary Cutaneous Anaplastic Large Cell Lymphoma** Approve for 3 years in patients with relapsed/refractory disease with central nervous system involvement.
19. **Rhabdomyosarcoma.** Approve for 3 years.
20. **Small Cell Lung Cancer.** Approve for 3 years if the patient has tried one chemotherapy regimen.
21. **Soft Tissue Sarcomas.** Approve for 3 years in patients with advanced, unresectable, or metastatic disease.
22. **Solitary Fibrous Tumor.** Approve for 3 years.
23. **Uterine Sarcomas.** Approve for 3 years in patients with metastatic, recurrent or medically inoperable disease.
24. **Uveal Melanoma.** Approve for 3 years for metastatic or unresectable disease.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of temozolomide capsules 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. Temodar[®] capsules [prescribing information]. White Station, NJ: Merck & Co., Inc (manufactured by Baxter Oncology GmbH, Halle, Germany); September 2015.
2. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (Version 2.2020 – April 30, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 5, 2020.

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4. The NCCN Cutaneous Melanoma Clinical Practice Guidelines in Oncology (Version 3.2020 – May 18, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 5, 2020.
5. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (Version 2.2020 – July 24, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 5, 2020.
6. The NCCN Primary Cutaneous Lymphoma Clinical Practice Guidelines in Oncology (Version 2.2020 – April 10, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 5, 2020.
7. The NCCN Drugs & Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 3, 2020. Search terms: temozolomide.
8. The NCCN -Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (Version 1.2021 – August 4, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 10, 2020.
9. The NCCN Soft Tissue Sarcoma Clinical Practice Guidelines in Oncology (Version 2.2020 – May 28, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 5, 2020.
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11. The NCCN Uveal Melanoma Clinical Practice Guidelines in Oncology (Version 1.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on August 10, 2020.