

## PRIOR AUTHORIZATION POLICY

**POLICY:** Oncology – Temozolomide Capsules Prior Authorization Policy

- Temodar® (temozolomide capsules – Merck, generic)

**REVIEW DATE:** 09/14/2022

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### OVERVIEW

Temozolomide, an alkylating agent, is indicated in adults for the following uses:<sup>1</sup>

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

### Guidelines

Temozolomide is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):

- **Bone Cancer:** NCCN guidelines (version 1.2023 – August 2, 2022) note temozolomide with irinotecan with or without vincristine as a preferred second-line therapy in patients with relapsed, refractory, or metastatic Ewing sarcoma (category 2A) or mesenchymal chondrosarcoma (category 2B).<sup>2</sup>
- **Central Nervous System (CNS) Tumors:** NCCN guidelines (version 1.2022 – June 2, 2022) note temozolomide as an option for a myriad of CNS cancers, including adult gliomas (i.e. isocitrate dehydrogenase [IDH] mutant oligodendroglioma, IDH-mutant astrocytoma, World Health Organization [WHO] Grade 1 glioma, and glioblastoma); intracranial or spinal ependymoma; gliosarcoma; primary CNS lymphoma; medulloblastoma; and brain metastases from solid tumors.<sup>3</sup>
- **Melanoma, Cutaneous:** NCCN guidelines (version 3.2022 – April 11, 2022) note temozolomide as a treatment option in patients with unresectable or metastatic melanoma as second-line or subsequent therapy for disease progression or after maximum clinical benefit from BRAF targeted therapy (category 2A).<sup>4</sup>
- **Neuroendocrine and Adrenal Tumors:** NCCN guidelines (version 1.2022 – May 23, 2022) recommend use of temozolomide for neuroendocrine tumors of the gastrointestinal tract, lung or thymus (carcinoid tumors), pancreas, poorly differentiated carcinomas, large or small cell neuroendocrine tumor, mixed neuroendocrine-non-neuroendocrine neoplasm, well differentiated grade 3 neuroendocrine tumor, and pheochromocytomas/paragangliomas (adrenal tumors) [category 2A].<sup>5</sup>
- **Pediatric CNS Cancers:** NCCN guidelines (version 1.2023 – July 12, 2022) recommend temozolomide for pediatric diffuse high-grade glioma in a variety of different clinical scenarios (category 2A).<sup>6</sup>
- **Primary Cutaneous Lymphomas:** NCCN guidelines (version 2.2022 – June 8, 2022) note temozolomide as a systemic treatment option, useful in certain circumstances for relapsed/refractory **mycosis fungoides/Sézary syndrome** and primary cutaneous anaplastic large cell lymphoma with CNS involvement (category 2A).<sup>7,8</sup>
- **Small Cell Lung Cancer:** NCCN guidelines (version 1.2023 – August 25, 2022) note temozolomide as a subsequent therapy option (category 2A).<sup>9</sup>
- **Soft Tissue Sarcomas:** NCCN guidelines (version 2.2022 – May 17, 2022) note single-agent temozolomide as a treatment option for subsequent line, palliative therapy in patients with advanced/metastatic soft tissue sarcomas subtypes with unknown histologies and for

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advanced/metastatic pleomorphic rhabdomyosarcoma. The guidelines also recommend temozolomide for non-pleomorphic rhabdomyosarcoma (in combination with vincristine and irinotecan) and solitary fibrous tumor (preferred therapy in combination with bevacizumab) [all category 2A].<sup>10</sup>

- **Uterine Neoplasms:** NCCN guidelines (version 1.2022 – November 4, 2021) note temozolomide as another recommended regimen for patients with metastatic or recurrent uterine sarcoma who have progressed on prior cytotoxic chemotherapy (category 2A).<sup>11</sup>
- **Uveal Melanoma:** NCCN guidelines (version 2.2022 – April 5, 2022) recommend temozolomide as a treatment option for patients with distant metastatic disease (category 2A).<sup>12</sup>

## **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 one of the following criteria:

### **FDA-Approved Indications**

1. **Anaplastic Astrocytoma.** Approve for 1 year.
2. **Glioblastoma Multiforme.** Approve for 1 year.  
Note: This includes glioblastoma and grade IV astrocytoma.

### **Other Uses with Supportive Evidence**

3. **Bone Cancer.** Approve for 1 year if the patient meets the following criteria (A and B):
  - A) Patient has tried one chemotherapy regimen; AND  
Note: Examples of a chemotherapy regimen include one or more of the following products: vincristine, doxorubicin, cyclophosphamide, ifosfamide, etoposide.
  - B) Patient has ONE of the following (i or ii):
    - i. Ewing sarcoma; OR
    - ii. Mesenchymal chondrosarcoma.
4. **Brain Metastases from Solid Tumors.** Approve for 1 year.
5. **Ependymoma, Intracranial or Spinal.** Approve for 1 year.
6. **Glioma, Other Types.** Approve for 1 year.  
Note: This includes pediatric diffuse high-grade glioma, oligodendroglioma, and low-grade glioma. For anaplastic astrocytoma and glioblastoma multiforme, refer to the respective criteria under the FDA-approved indications.
7. **Gliosarcoma.** Approve for 1 year.
8. **Medulloblastoma.** Approve for 1 year if the patient has tried one chemotherapy regimen.

Note: Examples of a chemotherapy regimen include one or more of the following products: cisplatin, cyclophosphamide, vincristine, lomustine.

**9. Melanoma.** Approve for 1 year if the patient has meets the following criteria (A and B):

- A) Patient has unresectable or metastatic melanoma; AND
- B) Patient has tried one systemic regimen.

Note: Examples of a systemic regimen include one or more of the following medications: Keytruda (pembrolizumab intravenous infusion), Opdivo (nivolumab intravenous infusion), Yervoy (ipilimumab intravenous infusion), Tafinlar (dabrafenib capsule), Mekinist (trametinib tablet), Zelboraf (vemurafenib tablet), Cotellic (cobimetinib tablet), Braftovi (encorafenib capsule), Mektovi (binimetinib tablet).

**10. Mycosis Fungoides/Sézary Syndrome.** Approve for 1 year if the patient meets the following criteria (A and B):

- A) Patient has tried one prior therapy; AND

Note: Examples of a prior therapy include topical carmustine, topical corticosteroids, topical imiquimod, topical retinoids, Adcetris (brentuximab vedotin intravenous infusion), gemcitabine.

- B) Patient has central nervous system (CNS) involvement.

**11. Neuroendocrine Tumors.** Approve for 1 year if the patient meets ONE of the following criteria (A, B, C, D, E, or F):

- A) Patient has carcinoid tumors or neuroendocrine tumor of gastrointestinal tract, lung or thymus; OR
- B) Patient has islet cell tumors or pancreatic neuroendocrine tumors; OR
- C) Patient has extrapulmonary poorly differentiated neuroendocrine carcinoma; OR
- D) Patient has large or small cell carcinoma; OR
- E) Patient has mixed neuroendocrine-non-neuroendocrine neoplasm; OR
- F) Patient has well differentiated grade 3 neuroendocrine tumor.

**12. Pheochromocytoma or Paragangliomas.** Approve for 1 year in patients with metastatic disease.

**13. Primary Central Nervous System Lymphoma.** Approve for 1 year.

**14. Primary Cutaneous Anaplastic Large Cell Lymphoma.** Approve for 1 year if the patient meets the following criteria (A and B):

- A) Patient has tried one prior therapy; AND

Note: Examples of a prior therapy include topical carmustine, topical corticosteroids, topical imiquimod, topical retinoids, Adcetris (brentuximab vedotin intravenous infusion), gemcitabine.

- B) Patient has central nervous system (CNS) involvement.

**15. Small Cell Lung Cancer.** Approve for 1 year if the patient has tried one systemic regimen.

Note: Examples of systemic regimen include one or more of the following products: cisplatin, etoposide, carboplatin, Tecentriq (atezolizumab intravenous infusion), Imfinzi (durvalumab intravenous infusion), irinotecan.

**16. Soft Tissue Sarcomas.** Approve for 1 year if the patient meets ONE of the following criteria (A or B):

- A) Patient has advanced, unresectable, or metastatic disease and ONE of the following diagnoses (i or ii):
  - i. Pleomorphic rhabdomyosarcoma; OR
  - ii. Soft tissue sarcoma with unknown histology; OR
- B) Patient has ONE of the following diagnoses (i or ii):
  - i. Non-pleomorphic rhabdomyosarcoma; OR

ii. Solitary fibrous tumor.

**17. Uterine Sarcomas.** Approve for 1 year if the patient has tried a chemotherapy regimen.

Note: Examples of chemotherapy regimen include one or more of the following products: doxorubicin, docetaxel, epirubicin, gemcitabine, ifosfamine, dacarbazine, vinorelbine.

**18. Uveal Melanoma.** Approve for 1 year if the patient has metastatic 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<sup>®</sup> capsules and intravenous infusion [prescribing information]. White Station, NJ: Merck; September 2019.
2. The NCCN Bone Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – August 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 12, 2022.
3. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2022 – June 2, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 12, 2022.
4. The NCCN Cutaneous Melanoma Clinical Practice Guidelines in Oncology (version 3.2022 – April 11, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 9, 2022.
5. The NCCN Neuroendocrine and Adrenal Tumors Clinical Practice Guidelines in Oncology (version 1.2022 – May 23, 2022) © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 9, 2022.
6. The NCCN Pediatric CNS Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – July 12, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 12, 2022.
7. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 9, 2022. Search terms: temozolomide.
8. The NCCN Primary Cutaneous Lymphoma Clinical Practice Guidelines in Oncology (version 2.2022 – June 8, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 9, 2022.
9. The NCCN Small Cell Lung Cancer Clinical Practice Guidelines in Oncology (version 1.2023– August 25, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 12, 2022.
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12. The NCCN Uveal Melanoma Clinical Practice Guidelines in Oncology (version 2.2022 – April 5, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on September 9, 2022.

