PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Temozolomide Capsules Prior Authorization Policy
- Temodar® (temozolomide capsules – Merck, generic)

REVIEW DATE: 06/26/2024

OVERVIEW
Temozolomide, an alkylating agent, is indicated in adults for the following uses:[1]
- **Anaplastic astrocytoma,**
  - Newly diagnosed as adjuvant treatment
  - Refractory
- **Glioblastoma**, newly diagnosed, concomitantly used with radiotherapy and then as maintenance therapy.

Guidelines
The National Comprehensive Cancer Network (NCCN) Compendium recommends use of temozolomide for the indications listed in the FDA-Approved Indications and Other Uses with Supportive Evidence sections.[2]

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 BOTH of the following (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 diagnosis (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: Examples of other types of gliomas include pediatric diffuse high-grade glioma, oligodendroglioma, low-grade glioma, circumscribed glioma; IDH-mutant astrocytoma. 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 recurrent or progressive disease.

9. **Melanoma.** Approve for 1 year if the patient meets BOTH of the following (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 BOTH of the following (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. **Neuroblastoma**. Approve for 1 year if the patient meets BOTH of the following (A and B):
    A) Patient has high risk disease; AND
    B) Patient will be using this medication in combination with chemoimmunotherapy.
    Note: Example of chemoimmunotherapy includes: irinotecan, Unituxin (dinutuximab intravenous infusion), and Leukine (sargramostim intravenous infusion).

12. **Neuroendocrine Tumors.** Approve for 1 year if the patient meets ONE of the following (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.

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

14. **Primary Central Nervous System Lymphoma.** Approve for 1 year.
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 has advanced or metastatic disease.

17. **Uterine Sarcomas**. Approve for 1 year if the patient has tried a chemotherapy regimen.
Note: Examples of a 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 unresectable or 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® capsules and intravenous infusion [prescribing information]. White Station, NJ: Merck; September 2023
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 20, 2024. Search term: temozolomide.