PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 10/11/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Temodar® (temozolomide capsules (Merck, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 (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: Examples of other types of gliomas include pediatric diffuse high-grade glioma, oligodendroglioma, low-grade glioma, and circumscribed 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 meets 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 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. **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.

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

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

14. **Soft Tissue Sarcomas.** Approve for 1 year if the patient meets ONE of the following (A or B):
    A) Patient has advanced or metastatic disease; OR
    B) Patient has ONE of the following diagnoses (i or ii):
        i. Non-pleomorphic rhabdomyosarcoma; OR
        ii. Solitary fibrous tumor.

15. **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.

16. **Uveal Melanoma.** Approve for 1 year if the patient has unresectable or metastatic disease.

CONDITIONS NOT COVERED

- **Temodar® (temozolomide capsules (Merck, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Temodar® capsules and intravenous infusion [prescribing information]. White Station, NJ: Merck; September 2023
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 3, 2023. Search term: temozolomide.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Anaplastic Gliomas:** This condition of approval was removed. **Glioma, Other Types**: The condition of approval of "low-grade glioma" was renamed to "glioma, other types." The requirement that the patient has World Health Organization (WHO) Grade I or II glioma was removed. A note was added with types of glioma and to refer to the respective criteria under the FDA-approved indications for anaplastic astrocytoma and glioblastoma multiforme. **Melanoma:** The requirement of trial of systemic regimen was added. A note was added with examples of a systemic regimen. **Neuroendocrine Tumors**: The words "extrapulmonary" and "neuroendocrine carcinoma" were added to the condition "poorly differentiated." The condition "large or small cell (other than lung)" was reworded to "large or small cell carcinoma." The following condition was added: mixed neuroendocrine-non-neuroendocrine neoplasm. **Soft Tissue Sarcoma:** For the criteria from patients with advanced, unresectable, or metastatic disease, angiosarcoma was removed and pleomorphic rhabdomyosarcoma was added.	09/14/2022
Annual Revision	The overview section was updated to include the new labeled indication of "newly diagnosed anaplastic astrocytoma as adjuvant treatment." **Glioma, Other Types**: The note was updated to state "examples of glioma" and circumscribed glioma was added. **Pheochromocytoma or Paragangliomas**: The criterion which states "patient has metastatic disease" was updated to state "patient has unresectable or metastatic disease." **Primary Cutaneous Anaplastic Large Cell Lymphoma:** This condition for approval was removed. **Soft Tissue Sarcoma:** The criteria which states "patient has advanced, unresectable, or metastatic disease and one of the following diagnoses: pleomorphic rhabdomyosarcoma or soft tissue sarcoma with unknown histology" was updated to state "patient has advanced or metastatic disease." **Uveal Melanoma:** The criterion which states that patient has metastatic disease was updated to state "patient has unresectable or metastatic disease."	10/11/2023