PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 06/18/2025

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. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. 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 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, high-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 meets ONE of the following (i or ii):
  i. Patient has tried one systemic regimen; OR
  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 and tablet for oral suspension), Mekinist (trametinib tablet and oral solution), Zelboraf (vemurafenib tablet), Cotellic (cobimetinib tablet), Braftovi (encorafenib capsule), Mektovi (binimetinib tablet).
  ii. Patient is not a candidate for a systemic regimen.

10. Mycosis Fungoides/Sézary Syndrome. Approve for 1 year if the patient meets BOTH of the following (A and B):
A) Patient has tried at least 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), Leukine (sargramostim intravenous infusion), and Danyelza (naxitamab-gqgk 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 COVERED

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

is(are) considered not medically necessary for ANY other use(s); 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. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 12, 2025. Search term: temozolomide.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	**Glioma, Other Types:** IDH-mutant astrocytoma was added to the Note of examples of other types of gliomas. **Medulloblastoma:** The requirement of trial of one chemotherapy regimen was removed. Criterion which states that patient has recurrent or progressive disease was added. **Neuroblastoma:** Condition of approval and criteria were added to Other Uses With Supportive Evidence. **Soft Tissue Sarcomas:** The requirement that the patient has non-pleomorphic rhabdomyosarcoma or solitary fibrous tumor was removed.	06/26/2024
Annual Revision	**Glioma, Other Types**: High-grade glioma was added to the Note of examples of other types of glioma. **Melanoma**: The following option for approval was added, "patient is not a candidate for a systemic regimen. **Mycosis Fungoides/Sézary Syndrome**: The requirement of trial of one prior therapy was clarified to state "at least one" prior therapy. **Neuroblastoma**: Danyelza (naxitamab-gqgk intravenous infusion) was added to the Note with examples of chemoimmunotherapy.	06/18/2025