Draft Revised Policy: Do Not Implement

Temozolomide (Temodar®), temozolomide

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:
POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications
Newly Diagnosed Glioblastoma
Temodar is indicated for the treatment of adults ~~patients~~ with newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment.

Anaplastic Astrocytoma
Temodar is indicated for the:

- adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma;
- treatment of adults with refractory anaplastic astrocytoma.

Compendial Uses

- Central nervous system (CNS) cancer
- CNS metastases from solid tumors
- Ewing sarcoma
- Neuroendocrine tumors of the pancreas, gastrointestinal tract, lung, and thymus
- Well-differentiated grade 3 neuroendocrine tumors
- Extrapulmonary Poorly differentiated (high grade) neuroendocrine carcinoma/large or small cell carcinoma
- Pheochromocytoma/paraganglioma
- Cutaneous melanoma
- Uveal melanoma
- Mycosis fungoides (MF)/Sézary syndrome (SS)
- Small cell lung cancer
- Soft tissue sarcoma
- Uterine sarcoma
- Neuroblastoma

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA ~~FOR INITIAL APPROVAL~~

Central nervous system (CNS) cancer

Authorization of 12 months may be granted for treatment of CNS cancers.

CNS metastases from solid tumors

Authorization of 12 months may be granted for treatment of brain metastases due to solid tumors.

Ewing sarcoma

Authorization of 12 months may be granted for treatment of Ewing sarcoma as second-line therapy in combination with irinotecan with or without vincristine for relapsed, progressive or metastatic disease.

Neuroendocrine tumors

Authorization of 12 months may be granted for treatment of neuroendocrine tumors.

~~**Extrapulmonary Poorly differentiated (high-grade) neuroendocrine carcinoma/large or small cell carcinoma**~~
~~Authorization of 12 months may be granted for treatment of extrapulmonary poorly differentiated (high-grade) neuroendocrine carcinoma or large or small cell carcinoma.~~

Pheochromocytoma/paraganglioma

Authorization of 12 months may be granted for treatment of pheochromocytoma or paraganglioma as single agent first-line therapy for unresectable or metastatic disease.

Cutaneous Melanoma

Authorization of 12 months may be granted for treatment of cutaneous melanoma as single agent subsequent therapy for metastatic or unresectable disease.

Uveal Melanoma

Authorization of 12 months may be granted for treatment of uveal melanoma for unresectable or metastatic disease as a single agent.

Mycosis fungoides (MF)/Sézary syndrome (SS)

Authorization of 12 months may be granted for treatment of MF or SS as single agent subsequent therapy for CNS involvement.

Small cell lung cancer (SCLC)

Authorization of 12 months may be granted for treatment of SCLC as single agent subsequent therapy for relapsed or primary progressive disease.

Soft tissue sarcoma (STS)

Authorization of 12 months may be granted for treatment of STS.

Uterine sarcoma

Authorization of 12 months may be granted for treatment of uterine sarcoma as single agent subsequent therapy for advanced, recurrent/metastatic or inoperable disease.

Neuroblastoma

Authorization of 12 months may be granted for treatment of high-risk neuroblastoma when used in combination with irinotecan, dinutuximab, and sargramostim.

CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section ~~II~~ when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Temodar [package insert]. Rahway, NJ: Merck & Co., Inc.; September 2023.
2. Temozolomide [package insert]. Durham, NC: Accord Healthcare, Inc.; December 2023.
3. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 17, 2025.
4. Temodar. Lexi-Drugs. UpToDate Lexidrug. UpToDate Inc. https://online.lexi.com. Accessed January 27, 2025.

EFFECTIVE DATE

ID_CHS