Reference number(s)
1665-A

Specialty Guideline Management temozolomide-Temodar

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Temodar	temozolomide

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[1,2]

Newly Diagnosed Glioblastoma

Temodar is indicated for the treatment of adults 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[3-4]

- 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

Central nervous system (CNS) cancer[1-3]

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

CNS metastases from solid tumors[4]

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

Ewing sarcoma[3]

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[3]

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

Pheochromocytoma/paraganglioma[3]

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[3]

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

Uveal Melanoma[3]

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)[3]

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)[3]

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)[3]

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

Uterine sarcoma[3]

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[3]

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

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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 when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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.