

Reference number(s)
1665-A

SPECIALTY GUIDELINE MANAGEMENT

Temodar (temozolomide) temozolomide (generic)

POLICY

I. 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.

A. FDA-Approved Indications

1. Newly Diagnosed Glioblastoma
Temodar is indicated for the treatment of adult patients with newly diagnosed glioblastoma concomitantly with radiotherapy and then as maintenance treatment.
2. Anaplastic Astrocytoma
Temodar is indicated for the:
 - a. adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma;
 - b. treatment of adults with refractory anaplastic astrocytoma.

B. Compendial Uses

1. Central nervous system (CNS) cancer
2. Ewing sarcoma
3. Neuroendocrine tumors of the pancreas, gastrointestinal tract, lung, and thymus
4. Well-differentiated grade 3 neuroendocrine tumors
5. Extrapulmonary Poorly differentiated (high grade) neuroendocrine carcinoma/large or small cell carcinoma
6. Pheochromocytoma/paraganglioma
7. Cutaneous melanoma
8. Uveal melanoma
9. Mycosis fungoides (MF)/Sézary syndrome (SS)
10. Small cell lung cancer
11. Soft tissue sarcoma
12. Uterine sarcoma
13. Neuroblastoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. **Central nervous system (CNS) cancer**

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

B. **Ewing sarcoma**

Authorization of 12 months may be granted for treatment of Ewing sarcoma.

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C. Neuroendocrine tumors

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

D. 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.

E. Pheochromocytoma/paraganglioma

Authorization of 12 months may be granted for treatment of pheochromocytoma or paraganglioma.

F. Cutaneous Melanoma

Authorization of 12 months may be granted for treatment of cutaneous melanoma for metastatic or unresectable disease.

G. Uveal Melanoma

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

H. Mycosis fungoides (MF)/Sézary syndrome (SS)

Authorization of 12 months may be granted for treatment of MF or SS.

I. Small cell lung cancer (SCLC)

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

J. Soft tissue sarcoma (STS)

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

K. Uterine sarcoma

Authorization of 12 months may be granted for treatment of uterine sarcoma.

L. Neuroblastoma

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

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

1. Temodar [package insert]. Rahway, NJ: Merck & Co., Inc.; September 2023.
2. Temozolomide [package insert]. Durham, NC: Accord Healthcare, Inc.; October 2021.
3. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: <https://www.nccn.org>. Accessed July 9, 2024.