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. Refractory Anaplastic Astrocytoma
   Temodar is indicated for the treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

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

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.

C. Neuroendocrine tumors of the pancreas, gastrointestinal tract, lung, and thymus
Authorization of 12 months may be granted for treatment of neuroendocrine tumors of the pancreas, gastrointestinal tract, lung, or thymus.

D. Poorly differentiated (high-grade) neuroendocrine carcinoma/large or small cell carcinoma
Authorization of 12 months may be granted for treatment of 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 distant 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.

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]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2019.
2. Temozolomide [package insert]. Durham, NC: Accord Healthcare, Inc.; March 2020.
3. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 5, 2021.