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 Multiforme
   Temodar is indicated for the treatment of adult patients with newly diagnosed glioblastoma multiforme 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, i.e., patients 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 pancreas, gastrointestinal tract, lung, and thymus
4. Poorly differentiated (high grade) neuroendocrine tumors/large or small cell carcinoma
5. Pheochromocytoma/paraganglioma
6. Melanoma[2]
7. Mycosis fungoides/Sézary syndrome
8. Small cell lung cancer
9. Soft tissue sarcoma
10. Uterine sarcoma
11. Primary cutaneous anaplastic large cell lymphoma (ALCL)

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 pancreas, gastrointestinal tract, lung, and thymus

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

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

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

F. Melanoma
Authorization of 12 months may be granted for treatment of metastatic or unresectable melanoma.

G. Mycosis fungoides/Sezary syndrome
Authorization of 12 months may be granted for treatment of mycosis fungoides/Sezary syndrome.

H. Small cell lung cancer (SCLC)
Authorization of 12 months may be granted for treatment of SCLC.

I. Soft tissue sarcoma (STS)
Authorization of 12 months may be granted for treatment of STS.

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

K. Primary cutaneous anaplastic large cell lymphoma (ALCL)
Authorization of 12 months may be granted for treatment of primary cutaneous ALCL.

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 who have not experienced disease progression or an unacceptable toxicity.

IV. REFERENCES

1. Temodar [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; October 2017.
2. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed September 28, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 2.2018). © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. January 29, 2019.
4. The NCCN Clinical Practice Guidelines in Oncology® Soft Tissue Sarcoma (Version 1.2019). © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. January 29, 2019.
5. The NCCN Clinical Practice Guidelines in Oncology® Neuroendocrine and adrenal tumors (Version 4.2018). © 2019 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 29, 2019.