

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:
  - a. Anaplastic gliomas
  - b. Intracranial and spinal ependymoma
  - c. Supratentorial astrocytoma/oligodendroglioma
  - d. Medulloblastoma
  - e. Brain metastases
  - f. Primary CNS lymphoma
2. Ewing sarcoma
3. Neuroendocrine tumors of pancreas, gastrointestinal tract, lung, and thymus
4. Pheochromocytoma/paraganglioma
5. Melanoma
6. Mycosis fungoides/Sézary syndrome
7. Small cell lung cancer
8. Soft tissue sarcoma:
  - a. Angiosarcoma
  - b. Retroperitoneal/intra-abdominal
  - c. Rhabdomyosarcoma
  - d. Solitary fibrous tumor and hemangiopericytoma
  - e. Of the extremity/trunk, head/neck
9. Uterine sarcoma

All other indications are considered experimental/investigational and are not a covered benefit.

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## II. CRITERIA FOR INITIAL APPROVAL

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

Authorization of 12 months may be granted for treatment of any of the following CNS cancers:

1. Glioblastoma
2. Refractory anaplastic astrocytoma
3. Anaplastic glioma
4. Intracranial and spinal ependymoma
5. Supratentorial astrocytoma/oligodendroglioma
6. Medulloblastoma
7. Brain metastases
8. Primary CNS lymphoma (PCNSL)

### 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. Pheochromocytoma/paraganglioma

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

### E. Melanoma

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

### F. Mycosis fungoides/Sezary syndrome

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

### G. Small cell lung cancer (SCLC)

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

### H. Soft tissue sarcoma (STS)

Authorization of 12 months may be granted for treatment of any of the following STS:

1. Angiosarcoma
2. Retroperitoneal/intra-abdominal STS
3. Rhabdomyosarcoma
4. Solitary fibrous tumor and hemangiopericytoma
5. STS of the extremity/trunk, head/neck

### I. Uterine sarcoma

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

## III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

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#### 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 January 12, 2018.
3. The NCCN Clinical Practice Guidelines in Oncology® Central Nervous System Cancers (Version 1.2017). © 2017 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed January 12, 2018.