SPECIALTY GUIDELINE MANAGEMENT

Temodar
temozolomide

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-supratentorial primitive neuroectodermal tumors (PNET)
   e. CNS metastases
   f. Primary CNS lymphoma
2. Ewing's sarcoma
3. Lung neuroendocrine tumors
4. Melanoma
5. Mycosis fungoides/Sézary syndrome
6. Pancreatic neuroendocrine tumors
7. Dermatofibrosarcoma protuberans
8. Small cell lung cancer
9. Soft tissue sarcoma:
   a. Angiosarcoma
   b. Retroperitoneal/intra-abdominal
   c. Rhabdomyosarcoma
   d. Solitary fibrous tumor and hemangiopericytoma
   e. Of the extremity/trunk, head/neck
10. Uterine sarcoma

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

II. CRITERIA FOR INITIAL APPROVAL

A. Central nervous system (CNS) cancer

1. Glioblastoma
Authorization of 12 months may be granted for treatment of glioblastoma when temozolomide is prescribed for use in any of the following settings:
   a. As maintenance treatment
   b. As adjuvant treatment
   c. As a single agent or in combination with bevacizumab for treatment of recurrent disease

2. Anaplastic glioma
   Authorization of 12 months may be granted for treatment of anaplastic gliomas when temozolomide is prescribed for use in any of the following settings:
   a. As adjuvant treatment
   b. As a single agent or in combination with bevacizumab for treatment of recurrent disease

3. Intracranial and spinal ependymoma
   Authorization of 12 months may be granted for treatment of progressive disease in members prescribed temozolomide as a single agent.

4. Supratentorial astrocytoma/oligodendroglioma
   Authorization of 12 months may be granted for treatment of recurrent or progressive disease in members prescribed temozolomide as a single agent.

5. Medulloblastoma and supratentorial primitive neuroectodermal tumors (PNET)
   Authorization of 12 months may be granted for recurrence therapy in members who have received prior chemotherapy and are prescribed temozolomide as a single agent.

6. Brain metastases
   Authorization of 12 months may be granted for treatment of brain metastases in members prescribed temozolomide as a single agent.

7. Primary CNS lymphoma (PCNSL)
   Authorization of 12 months may be granted for treatment of PCNSL.

B. Ewing’s sarcoma
   Authorization of 12 months may be granted for treatment of Ewing’s sarcoma in members prescribed temozolomide in combination with irinotecan.

C. Lung neuroendocrine tumors
   Authorization of 12 months may be granted for treatment of lung neuroendocrine tumors in members prescribed temozolomide as a single agent or in combination with capecitabine.

D. Pancreatic neuroendocrine tumors
   Authorization of 12 months may be granted for treatment of pancreatic neuroendocrine tumors in members prescribed temozolomide as a single agent or in combination with capecitabine.

E. Melanoma
   Authorization of 12 months may be granted for treatment of metastatic or unresectable melanoma in members prescribed temozolomide as a single agent.

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

G. Dermatofibrosarcoma protuberans (DFSP)
   Authorization of 12 months may be granted for treatment of metastatic disease.

H. Small cell lung cancer (SCLC)
   Authorization of 12 months may be granted for treatment of SCLC in members prescribed temozolomide as a single agent.
I. Soft tissue sarcoma (STS)
   1. Angiosarcoma
      Authorization of 12 months may be granted for treatment of angiosarcoma in members prescribed
temozolomide as a single agent.

   2. Retroperitoneal/intra-abdominal STS
      Authorization of 12 months may be granted for treatment of retroperitoneal/intra-abdominal STS in
members prescribed temozolomide as a single agent.

   3. Rhabdomyosarcoma
      Authorization of 12 months may be granted for treatment of rhabdomyosarcoma.

   4. Solitary fibrous tumor and hemangiopericytoma
      Authorization of 12 months may be granted for treatment of solitary fibrous tumor or
hemangiopericytoma in members prescribed temozolomide in combination with bevacizumab.

   5. STS of the extremity/trunk, head/neck
      Authorization of 12 months may be granted for treatment of STS of the extremity/trunk or head/neck
in members prescribed temozolomide as a single agent.

J. Uterine sarcoma
   Authorization of 12 months may be granted for treatment of uterine sarcoma in members prescribed
temozolomide as a single agent.

III. CONTINUATION OF THERAPY

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

IV. DOSAGE AND ADMINISTRATION

   Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia,
and/or evidence-based practice guidelines.

V. REFERENCES