Medical Policy:

Temodar (temozolomide) Intravenous

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.170	February 11, 2025	July 15, 2019

Definitions

Temodar is an alkylating antineoplastic agent. Temodar undergoes rapid chemical conversion at physiologic pH to the active compound, monomethyl triazeno imidazole carboxamide (MTIC). The cytotoxicity of MTIC is thought to be due primarily to methylation of DNA at the O6 and N7 positions of guanine. The formation of Omethylguanine inhibits DNA replication through errant repair of the methyladduct and causes cell death via stimulation of p53 and apoptosis. Temodar is cell-cycle non-specific; however, cell cycle arrest usually occurs between the G2- and M-phases. The combination of Temodar (temozolomide) and radiation therapy results in additive effects.

Length of Authorization

Coverage will be provided for 6 months and may be renewed.

- Glioblastoma may be authorized up to a maximum of thirty-five (35) weeks of therapy.
- Adjuvant therapy for Anaplastic Astrocytoma may be authorized up to a maximum of forty-eight (48) weeks of therapy

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- Glioblastoma:

  (concomitant use phase) – 200 billable units daily for a total of 49 days

  (maintenance use phase) – 400 billable units once daily on days 1 to 5 of a 28-Day cycle for cycle 1. Then 500 billable units once daily on days 1 to 5 of a 28-day Cycle for cycles 2-12.
- All other indications: 2500 billable units every 28 days

Guideline

I. Initial Approval Criteria

1. ***Temodar*** *may be considered medically necessary if one of the below conditions are met* ***AND*** *use is consistent with the medical necessity criteria that follows:*
   A. Patient age is ≥ 18 years old; **AND**
   B. Prescribed by, or in consultation with, an oncologist; **AND**
   C. Patient has medical documentation for **ONE** of the following indications:
      i. **Glioblastoma**
         a. Patient has newly diagnosed disease; **AND**
         b. Used concomitantly with radiotherapy therapy and then as a single agent as maintenance treatment; **AND**
         c. Patient will receive Pneumocystis pneumonia (PCP) prophylaxis during the concomitant use with radiotherapy phase *(Note: PCP prophylaxis will be continued during the maintenance phase in patients who develop lymphopenia until resolution to Grade 1 or less)*; **OR**
      ii. **Anaplastic Astrocytoma**
         a. Used as a single agent; **AND**
         b. Patient has refractory disease that has progressed on a nitrosourea and procarbazine-containing regimen; **OR**
         c. Used as adjuvant treatment for newly diagnosed disease

Limitations/Exclusions

Temodar is not considered medically necessary for when any of the following selection criteria is met:

1. Disease progression while on Temodar (temozolimide).
2. Dosing exceeds single dose limit of 200 mg/m^2/day.
3. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. Renewal Criteria

1. Patient continues to meet INITIAL APPROVAL CRITERIA; **AND**
2. Tumor response with disease stabilization or reduction of tumor size and spread; **AND**
3. Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression [e.g., pancytopenia, leukopenia, anemia, neutropenia (absolute neutrophil count < 1.5 x 109/L), thrombocytopenia (platelet count < 100 x 109/L), etc.], myelodysplastic syndrome or secondary malignancy, pneumocystis pneumonia (PCP), severe hepatotoxicity, etc.
4. **Glioblastoma**
   • Patient has not exceeded a maximum of thirty-five (35) weeks of therapy

5. **Anaplastic Astrocytoma (adjuvant therapy)**
   - Patient has not exceeded a maximum of forty-eight (48) weeks of therapy

Dosage/Administration

Indication	Dose
Glioblastoma	***Concomitant phase****:* 75 mg/m^2 daily for up to 49 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions) followed by maintenance Temodar for 6 cycles. ***Maintenance phase:*** ***Cycle 1:*** Four weeks after completing the Temodar+RT phase, Temodar is administered for an additional 6 cycles of maintenance treatment. Dosage in Cycle 1 (maintenance) is 150 mg/m^2 once daily for 5 days followed by 23 days without treatment. ***Cycles 2-6:*** At the start of Cycle 2, the dose can be escalated to 200 mg/m^2. The dose remains at 200 mg/m^2 per day for the first 5 days of each subsequent cycle except if toxicity occurs. If the dose was not escalated at Cycle 2, escalation should not be done in subsequent cycles.
Anaplastic astrocytoma	Adjuvant Treatment of Newly Diagnosed Disease • Cycle 1: Administer 150 mg/m² intravenously once daily on days 1 to 5 of a 28-day cycle (beginning 4 weeks after the end of radiotherapy). • Cycles 2 to 12: Administer up to 200 mg/m² intravenously once daily on days 1 to 5 of a 28-day cycle. Refractory Disease • Cycle 1: Administer 150 mg/m² intravenously once daily on days 1 to 5 of a 28-day cycle. • Cycle 2 and beyond: Administer up to 200 mg/m² intravenously once daily on days 1 to 5 of a 28-day cycle until disease progression or unacceptable toxicity

Applicable Procedure Codes

Code	Description
J9328	Injection, temozolomide, 1 mg, 1 billable unit = 1 mg

Applicable NDCs

Code	Description
00085-1381-xx	Temodar single use vial; 100 mg powder for solution

ICD-10 Diagnoses

Code	Description
C71.0 - C71.9	Malignant neoplasm of brain [intracranial ependymoma] [adult low-hyphengrade infiltrative supratentorial astrocytoma/oligodendroglioma] [adult medulloblastoma or supratentorial primitive neuroectodermal tumors (PNET)] [anaplastic gliomas] [glioblastoma]
C72.0 C72.9	Malignant neoplasm of central nervous system [anaplastic gliomas, glioblastoma, adult low-hyphengrade infiltrative supratentorial astrocytoma/oligodendroglioma (excluding pilocytic astrocytoma)]

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	2/11/25	Annual Review: Updated length of authorization and dosage limits; Initial Criteria: Glioblastoma Added: “Patient has newly diagnosed disease; AND Used concomitantly with radiotherapy therapy and then as a single agent as maintenance treatment; AND Patient will receive Pneumocystis pneumonia (PCP) prophylaxis during the concomitant use with radiotherapy phase (Note: PCP prophylaxis will be continued during the maintenance phase in patients who develop lymphopenia until resolution to Grade 1 or less); OR” Anaplastic Astrocytoma Added: “Used as a single agent; AND Patient has refractory disease that has progressed on a nitrosourea and procarbazine-containing regimen; OR Used as adjuvant treatment for newly diagnosed disease” Renewal Criteria: added: “Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelosuppression [e.g., pancytopenia, leukopenia, anemia, neutropenia (absolute neutrophil count < 1.5 x 109/L), thrombocytopenia (platelet count < 100 x 109/L), etc.], myelodysplastic syndrome or secondary malignancy, pneumocystis pneumonia (PCP), severe hepatotoxicity, etc. Glioblastoma • Patient has not exceeded a maximum of thirty-five (35) weeks of therapy Anaplastic Astrocytoma (adjuvant therapy) • Patient has not exceeded a maximum of forty-eight (48) weeks of therapy” Updated dosage chart
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	5/3/2023	Annual Review: no criteria changes
EmblemHealth & ConnectiCare	1/13/2023	Transfer to New Template
EmblemHealth & ConnectiCare	7/15/2019	New Policy

References

1. Product Information: TEMODAR® oral capsules, IV injection, temozolomide oral capsules, IV injection. Schering Corporation, Whitehouse Station, NJ, 2011.