Medical Policy:

Temodar (temozolomide)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.170	January 2, 2024	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.

Dosing Limits [Medical Benefit]

Max Units (per dose and over time):

- 200 mg/m^2/day (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. Dose does not exceed 200 mg/m^2/day; **AND**
   D. Patient has medical documentation for **ONE** of the following indications:
      i. Glioblastoma
      ii. Anaplastic Astrocytoma

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.
2. Tumor response with disease stabilization or reduction of tumor size and spread.

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	Initial dose is 150 mg/m^2 once daily for 5 consecutive days per 28-day treatment cycle.

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	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.