

## Medical Policy:

### Temodar (temozolomide)

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.170	January 2, 2024	July 15, 2019

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The treating physician or primary care provider must submit to EmblemHealth, or ConnectiCare, as applicable (hereinafter jointly referred to as “EmblemHealth”), the clinical evidence that the member meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request preauthorization or post-payment review. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. This clinical policy is not intended to pre-empt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Health care providers are expected to exercise their medical judgment in rendering appropriate care.

EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary.

If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test or procedure over another. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication.

EmblemHealth may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice. EmblemHealth Services Company, LLC, has adopted this policy in providing management, administrative and other services to EmblemHealth Plan, Inc., EmblemHealth Insurance Company, EmblemHealth Services Company, LLC, and Health Insurance Plan of Greater New York (HIP) related to health benefit plans offered by these entities. ConnectiCare, an EmblemHealth company, has also adopted this policy. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

## 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<sup>2</sup>/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<sup>2</sup>/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<sup>2</sup>/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	<p><b><u>Concomitant phase:</u></b> 75 mg/m<sup>2</sup> daily for up to 49 days concomitant with focal radiotherapy (60 Gy administered in 30 fractions) followed by maintenance Temodar for 6 cycles.</p> <p><b><u>Maintenance phase:</u></b> <b>Cycle 1:</b> 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<sup>2</sup> once daily for 5 days followed by 23 days without treatment. <b>Cycles 2-6:</b> At the start of Cycle 2, the dose can be escalated to 200 mg/m<sup>2</sup>. The dose remains at 200 mg/m<sup>2</sup> 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.</p>
Anaplastic astrocytoma	Initial dose is 150 mg/m <sup>2</sup> once daily for 5 consecutive days per 28-day treatment cycle.

## Applicable Procedure Codes

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