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Section:	Prescription Drugs	**Effective Date:**	January 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 1, 2021
Subject:	Temodar	**Page:**	1 of 3

Last Review Date: December 12, 2025

Temodar capsules

Description

Temodar (temozolomide) capsules

Temodar injection is not included in this policy

Background
Temodar (temozolomide) is an alkylating drug. Temozolomide is not directly active but undergoes rapid nonenzymatic conversion at physiologic pH to the reactive compound 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC). The cytotoxicity of MTIC is thought be primarily due to alkylation of DNA (1).

Regulatory Status
FDA-approved indications: Temodar is indicated for: (1)

- Glioblastoma multiforme (GBM)
- Astrocytoma

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Temodar may be considered **medically necessary** if the conditions indicated below are met.

Temodar may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Glioblastoma multiforme (GBM)
2. Astrocytoma

AND the following for **ALL** diagnoses:

a. Patient **MUST** have tried the preferred product (generic Temodar: temozolomide) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Temodar (temozolomide) is an alkylating drug. Temozolomide is not directly active but undergoes rapid nonenzymatic conversion at physiologic pH to the reactive compound 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC). The cytotoxicity of MTIC is thought be primarily due to alkylation of DNA (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Temodar while maintaining optimal therapeutic outcomes.

References

1. Temodar [package insert]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp.; September 2023.
2. NCCN Drugs & Biologics Compendium® Temozolomide 2025. National Comprehensive Cancer Network, Inc. Accessed on October 29, 2025.

Policy History

Date	Action
December 2020	Addition to PA. Annual review
December 2021	Annual review and reference update
December 2022	Annual review and reference update
September 2023	Annual review and reference update
September 2024	Annual review and reference update
December 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 12, 2025 and is effective on January 1, 2026.