

TEMODAR CAPSULES (temozolomide)

Temodar injection is not included in this policy

RATIONALE FOR INCLUSION IN PA PROGRAM

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-methyltriazene-1-yl)-imidazole-4-carboxamide (MTIC). The cytotoxicity of MTIC is thought to be primarily due to alkylation of DNA (1).

Regulatory Status

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

- Glioblastoma multiforme (GBM)
- Astrocytoma

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-methyltriazene-1-yl)-imidazole-4-carboxamide (MTIC). The cytotoxicity of MTIC is thought to 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 2024. National Comprehensive Cancer Network, Inc. Accessed on July 11, 2024