

Specialty Pharmacy Program

Temodar® (temozolomide)

DESCRIPTION

Temodar is an alkylating agent that is indicated for the treatment of newly diagnosed glioblastoma multiforme and refractory anaplastic astrocytoma.

APPROVAL DURATION

Approval duration: 1 year

APPROVAL CRITERIA

FDA-Approved Indication(s)

1. Treatment of adult patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.
2. Treatment of adult patients with refractory anaplastic astrocytoma (ie, patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine).

Off-Label Indication(s)

Requests for off-label use of Temodar will be reviewed and approved when sufficiently supported by evidence from major compendia, published peer-reviewed medical literature, nationally accepted practice guidelines, or expert consensus statements. The major compendia that are recognized include AHFS® Drug Information, Thomson Micromedex®, National Comprehensive Cancer Network Drugs and Biologics Compendium™, and Clinical Pharmacology.