

Temodar[®] (temozolomide) – Updated indication

- On September 14, 2023, the [FDA announced](#) the [approval](#) of Merck's [Temodar \(temozolomide\)](#), for the adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma and treatment of adults with refractory anaplastic astrocytoma.
 - Temodar was previously approved for treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.
- One approved indication for Temodar remains the same: treatment of adults with newly diagnosed glioblastoma, concomitantly with radiotherapy and then as maintenance treatment.
- The approval of the updated labeling for Temodar was under Project Renewal, an Oncology Center of Excellence initiative aimed at updating labeling information for older oncology drugs to ensure information is clinically meaningful and scientifically up-to-date.
 - Project Renewal is a collaborative program that leverages external oncology experts and early-career scientists to review existing published literature and gain first-hand experience in the selection, curation, and evaluation of evidence for independent FDA review.
 - Project Renewal is intended to keep older, commonly prescribed oncology drugs' labeling up-to-date, while providing transparency on FDA's evaluation process and evidentiary standards, and improving awareness of drug labeling as an information resource.
- The approval of Temodar for adjuvant treatment of newly diagnosed anaplastic astrocytoma was derived from studies of Temodar in the published literature. Temodar was evaluated in CATNON, a randomized, open-label study where the major efficacy outcome measure was overall survival.
- In addition to the updated labeling, additional labeling revisions include:
 - The dosage regimen is revised and updated for newly diagnosed glioblastoma and refractory anaplastic astrocytoma.
 - For Temodar capsules, information on risks from exposure to opened capsules is added under Warnings and Precautions.
- Refer to the Temodar drug label for complete dosing and administration recommendations.