



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

TEMOZOLOMIDE - PO

Generic	Brand	HICL	GCN	Exception/Other
TEMOZOLOMIDE - PO	TEMODAR - PO		92903 92893 92933 92913 98310 98311	

**This drug requires a written request for prior authorization.**

**GUIDELINES FOR USE**

1. Does the patient have one of the following diagnoses: metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC)?

If yes, **approve for 12 months by GPID.**

If no, do not approve.

**DENIAL TEXT:** Approval requires a diagnosis of metastatic melanoma, anaplastic astrocytoma, glioblastoma multiforme, or small cell lung cancer (SCLC).

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**RATIONALE**

Based on FDA approved indications and NCCN recommendations. Temodar is approved for the treatment of newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment; and refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine. NCCN recommends Temodar for SCLC patients with relapse <2-3 months, performance status 0-2 or relapse >2-3 up to 6 months (most useful if brain metastases are present); and for the treatment of metastatic melanoma. NCCN considers temozolomide to be a systemic therapy option for advanced or metastatic melanoma. No quantity limit is included within this guideline since there are multiple dosing regimens available, all of which are based on body surface area.

**FDA APPROVED INDICATIONS**

Temodar is an alkylating drug indicated for the treatment of adult patients with:

- Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment.
- Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

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REFERENCES

- National Comprehensive Cancer Network, Inc. NCCN Clinical Practice Guidelines in Oncology Melanoma. (Version 3.2012).
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology Small Cell Lung Cancer Version 2.2014. [Online] September 17, 2013. [Cited: September 25, 2013.] [http://www.nccn.org/professionals/physician\\_gls/pdf/sclc.pdf](http://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf)
- Schering Corporation, a subsidiary of Merck & Co., Inc. Temodar package insert. Whitehouse Station, NJ. February 2011.
- Thomson Healthcare. Monograph Name. DRUGDEX® System [database online]. Greenwood Village, CO. Available at: <https://www.thomsonhc.com/hcs/librarian/PFDefaultActionId/pf.LoginAction>. [Accessed: January 24, 2012].

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/27/15

Created: 02/12

Client Approval: 01/15

P&T Approval: 11/13