

Clinical Pharmacy Program Guidelines for Temodar

Program	Prior Authorization
Medication	Temodar [®] (temozolomide)
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2017
Effective Date	11/2017

1. Background:

Temodar[®] (temozolomide) is an alkylating drug indicated for treatment in patients with newly diagnosed glioblastoma multiforme concomitantly with radiotherapy and then as maintenance treatment.¹ It is also indicated for treatment of adult patients with refractory anaplastic astrocytoma who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine. The National Comprehensive Cancer Network (NCCN) also recommends Temodar for the treatment of CNS cancers - primary astrocytoma/oligodendroglioma or anaplastic glioma central nervous system tumors, ependymoma, metastatic central nervous system lesions, primary central nervous system lymphoma, supratentorial primitive neuroectodermal tumors, medulloblastoma; melanoma; dermatofibrosarcoma protuberans (DFSP); pancreatic neuroendocrine disorders; NHL – mycosis fungoides (MF) and Sézary syndrome (SS); soft tissue sarcoma (STS), Ewing’s sarcoma; mesenchymal chondrosarcoma; lung neuroendocrine tumors; pheochromocytoma/paraganglioma neuroendocrine tumors; uterine sarcoma; or small cell lung cancer (SCLC).²

2. Coverage Criteria:

<p>A. <u>Central Nervous Systems (CNS) Tumor</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Temodar will be approved based on <u>one</u> of the following diagnoses:</p> <ul style="list-style-type: none"> (1) Intracranial and Spinal Ependymoma (Excluding Subependymoma) (2) Low-Grade Infiltrative Supratentorial Astrocytoma/Oligodendroglioma (excluding pilocytic astrocytoma) (3) Medulloblastoma (4) Supratentorial Primitive Neuroectodermal Tumors (5) Anaplastic Gliomas (6) Glioblastoma (7) Metastatic lesions of the CNS (8) Primary CNS lymphoma <p>Authorization will be issued for 12 months.</p>
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2. Reauthorization

- a. Temodar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

B. Melanoma (off-label)

1. Initial Authorization

- a. Temodar** will be approved based on the following criterion:

(1) Diagnosis of melanoma

Authorization will be issued for 12 months.

2. Reauthorization

- a. Temodar** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

C. Neuroendocrine Tumors (off-label)

1. Initial Authorization

- a. Temodar** will be approved based on the following criterion:

(1) Diagnosis of one of the following types of neuroendocrine tumors:

- (a) GI tract, lung or thymus
- (b) Pancreatic neuroendocrine tumors
- (c) Pheochromocytoma/paraganglioma

Authorization will be issued for 12 months.

2. Reauthorization

- a. Temodar** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

D. Non-Hodgkin Lymphoma (NHL) (off-label)

1. Initial Authorization

- a. **Temodar** will be approved based on **one** of the following diagnoses:

- (1) Mycosis fungoides (MF)
(2) Sézary syndrome (SS)

Authorization will be issued for 12 months.

2. Reauthorization

- a. **Temodar** will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

E. Soft Tissue Sarcoma (off-label)

1. Initial Authorization

- a. **Temodar** will be approved based on **one** of the following:

- (1) Diagnosis of angiosarcoma
(2) Diagnosis of unresectable or progressive retroperitoneal/ intra-abdominal soft tissue sarcoma
(3) Diagnosis of rhabdomyosarcoma
(4) **Both** of the following:
(a) Diagnosis of soft tissue sarcoma of the extremity/ superficial trunk, Head/Neck
(b) **One** of the following:
i. Disease synchronous stage IV
ii. Disease has disseminated metastases
(5) **Both** of the following:
(a) Diagnosis of solitary fibrous tumor/ hemangiopericytoma
(b) Used in combination with Avastin (bevacizumab)

Authorization will be issued for 12 months.

2. Reauthorization

a. Temodar will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

F. Bone Cancer (off-label)

1. Initial Authorization

a. Temodar will be approved based on **all** of the following criteria:

- (1) Diagnosis of one of the following:

- (a) Ewing's sarcoma family of tumors
(b) Mesenchymal chondrosarcoma

-AND-

- (2) **One** of the following:

- (a) Disease has relapsed
(b) Disease is progressive following primary treatment
(c) Used as second-line therapy for metastatic disease

-AND-

- (3) Used in combination with Campostar (irinotecan)

Authorization will be issued for 12 months.

2. Reauthorization

a. Temodar will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

G.. Uterine Sarcoma (off-label)

1. Initial Authorization

a. Temodar will be approved based on the following criterion:

- (1) Diagnosis of uterine sarcoma

Authorization will be issued for 12 months.

2. Reauthorization

a. Temodar will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

H. Small Cell Lung Cancer (SCLC) (off-label)

1. Initial Authorization

a. Temodar will be approved based on **both** of the following criterion:

- (1) Diagnosis of small cell lung cancer (SCLC)

-AND-

- (2) **One** of the following:

- (a) Relapse within 6 months following complete or partial response or stable disease with initial treatment
- (b) Primary progressive disease

Authorization will be issued for 12 months.

2. Reauthorization

a. Temodar will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

I.. Non-Melanoma Skin Cancer (off-label)

1. Initial Authorization

a. Temodar will be approved based on the following criterion:

- (1) Diagnosis of metastatic dermatofibrosarcoma protuberans (DFSP)

Authorization will be issued for 12 months.

2. Reauthorization

a. Temodar will be approved based on the following criterion:

- (1) Patient does not show evidence of progressive disease while on Temodar therapy

Authorization will be issued for 12 months.

3. References:

1. Temodar [package insert]. Whitehouse Station, NJ: Schering Corporation, a subsidiary of Merck & Co., Inc.; April 2017.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August 3, 2017.

Program	Prior Authorization - Temodar (temozolomide)
Change Control	
Date	Change
9/2013	New guideline.
12/2015	Annual Review
9/2016	Updated clinical criteria to align with E&I notification policy and updated policy template.
9/2017	Annual review. Revised criteria for bone cancer. Consolidated criteria for neuroendocrine tumors. Updated background and references.