UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Temodar

Program	Prior Authorization
Medication	Temodar® (temozolomide)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2013
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

1. Background:

Temodar (temozolomide) is an alkylating drug indicated for treatment in patients with newly diagnosed glioblastoma 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 - infiltrative supratentorial astrocytoma/oligodendroglioma or anaplastic glioma, intracranial and spinal ependymoma, , limited and extensive brain metastases, glioblastoma, primary central nervous system lymphoma, medulloblastoma; cutaneous melanoma and uveal melanoma; pancreatic neuroendocrine disorders; primary cutaneous lymphomas – mycosis fungoides (MF), Sézary syndrome (SS) and anaplastic large cell lymphoma; soft tissue sarcoma (STS), Ewing's sarcoma; mesenchymal chondrosarcoma; lung neuroendocrine tumors; pheochromocytoma/paraganglioma, carcinoid syndrome, neuroendocrine and adrenal tumors; uterine sarcoma; or small cell lung cancer (SCLC).[2]

2. Coverage Criteria:

A. <u>Central Nervous Systems (CNS) Tumor</u>

1. <u>Initial Authorization</u>

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

(1) Diagnosis of **one** of the following types of central nervous system tumors:
- (a) Intracranial and Spinal Ependymoma (excluding Subependymoma)
- (b) Low-Grade Infiltrative Supratentorial Astrocytoma/Oligodendroglioma
- (c) Medulloblastoma
- (d) Anaplastic Gliomas
- (e) Glioblastoma
- (f) Limited or extensive brain metastases

(g) Primary CNS lymphoma

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.

B. Cutaneous Melanoma/Uveal Melanoma

1. Initial Authorization

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

(1) Diagnosis of **one** of the following types of melanoma:

(a) Metastatic cutaneous melanoma
(b) Metastatic uveal 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 and Adrenal Tumors

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) Bronchopulmonary/thymic disease
(b) Poorly controlled carcinoid syndrome in lung or thymus
(c) Pancreas
(d) Pheochromocytoma/paraganglioma

(e) Poorly differentiated (High Grade)/ large or small cell

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. Primary Cutaneous Lymphomas

1. **Initial Authorization**

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

(1) Diagnosis of **one** of the following types of primary cutaneous lymphomas

~~(a)~~ Mycosis fungoides (MF)
(b) Sézary syndrome (SS)
(c) Primary cutaneous anaplastic large cell lymphoma

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

1. **Initial Authorization**

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

(1) Diagnosis of angiosarcoma
(2) Diagnosis of unresectable or progressive retroperitoneal/intra-abdominal soft tissue sarcoma

(3) Diagnosis of rhabdomyosarcoma
(4) Undifferentiated pleomorphic sarcoma
(5) **Both** of the following:
  (a) Diagnosis of soft tissue sarcoma of the extremity/superficial trunk, Head/Neck
  (b) **One** of the following:
    i. Disease is stage IV
    ii. Disease has disseminated metastases
(6) **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

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

1. Initial Authorization

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

(1) Diagnosis of recurrent or metastatic 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)

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. NCCN Recommended Regimens

1. Initial Authorization

a. **Temodar** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Temodar therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Temodar [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; November 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 30,2020.

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.
9/2018	Annual review. Revised coverage criteria. Added coverage for uveal melanoma. Removed coverage for neuroectodermal tumors, DFSP. Added NCCN Recommended Regimen criteria. Updated background and references.
9/2019	Revised coverage rationale to align with NCCN guidance. Updated background and references.
9/2020	Annual review. Revised coverage rationale to align with NCCN guidelines. Updated background and references. Added Additional Clinical Rules section.