UnitedHealthcare Community Plan

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:

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

1. <u>Initial Authorization</u>

a. Temodar will be approved based on **<u>one</u>** of the following diagnoses:

(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

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. **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.

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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.