UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1106-12
Program	Prior Authorization/Notification
Medication	Temodar® (temozolomide)
P&T Approval Date	8/2009, 6/2009, 6/2010, 9/2010, 12/2010, 9/2011, 1/2012, 8/2012, 7/2013, 11/2014, 11/2015, 9/2016, 9/2017, 9/2018, 9/2019, 9/2020, 10/2021, 10/2022, 10/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Temodar® (temozolomide) is an alkylating drug indicated for treatment of adult 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 and as adjuvant treatment with newly diagnosed anaplastic astrocytoma. 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, uveal melanoma, and mucosal melanoma; pancreatic neuroendocrine disorders; primary cutaneous lymphomas – mycosis fungoides (MF) and Sézary syndrome (SS); 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]

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

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

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

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

1. **<u>Initial Authorization</u>**

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

(1) Diagnosis of **one** of the following types of central nervous systems tumor:

(a) Intracranial and Spinal Ependymoma (Excluding Subependymoma)
(b) World Health Organization (WHO) Grade 2, 3, or 4 isocitrate dehydrogenase (IDH)-mutant Astrocytoma
(c) WHO Grade 2 or 3 IDH-mutant, 1p19q Codeleted Oligodendroglioma
(d) Medulloblastoma
(e) Circumscribed Glioma
(f) Glioblastoma
(g) Limited or extensive brain metastases
(h) 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.

C. 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 or unresectable cutaneous melanoma
(b) Metastatic or unresectable uveal melanoma
(c) Mucosal 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.

D. Neuroendocrine and Adrenal Tumors

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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 gastrointestinal tract, lung, or thymus
         (c) Pancreas
         (d) Pheochromocytoma/paraganglioma
         (e) Poorly differentiated (High Grade)/ large or small cell
         (f) Well differentiated grade 3 neuroendocrine tumors

      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. 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)

      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. Soft Tissue Sarcoma

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1. **Initial Authorization**

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

      (1) Diagnosis of recurrent unresectable or stage IV retroperitoneal/intra-abdominal soft tissue sarcoma
      (2) Diagnosis of rhabdomyosarcoma
      (3) Undifferentiated pleomorphic sarcoma
      (4) **Both** of the following:
         (a) Diagnosis of soft tissue sarcoma of the extremity/body wall, head/neck
         (b) **One** of the following:
            i. Disease is stage IV
            ii. Disease has disseminated metastases
      (5) Diagnosis of solitary fibrous tumor/hemangiopericytoma

      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. Bone Cancer

1. **Initial Authorization**

   a. **Temodar** will be approved based **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)

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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. 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.

I. 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 following complete or partial response or stable disease with primary treatment
(b) Primary progressive disease

Authorization will be issued for 12 months.

2. **Reauthorization**

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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.

J. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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]. Rahway, NJ: Merck Sharp & Dohme Corp.; September 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/compendia-templates/compendia/nccn-compendia. Accessed September 13, 2024.

Program	Prior Authorization/Notification - Temodar (temozolomide)
Change Control	
11/2014	Annual review. Expanded criteria for CNS, soft tissue and bone cancer. Clarified NHL and Lung Neuroendocrine Tumor criteria.
11/2015	Annual review. Revised bone cancer; soft tissue sarcoma; SCLC; non-melanoma sarcoma; lung and neuroendocrine tumors coverage criteria. Updated background and references.
9/2016	Annual review. Changed Member to Patient. Revised criteria for Soft Tissue Sarcoma and bone cancer. Added coverage criteria for pheochromocytoma/paraganglioma neuroendocrine tumors. Updated background and references.
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

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	melanoma. Removed coverage for neuroectodermal tumors, DFSP. Updated background and references.
9/2019	Annual review. Revised coverage rationale to align with NCCN guidelines. Updated background and references. Added general NCCN recommended review criteria.
9/2020	Annual review. Revised coverage rationale to align with NCCN guidelines. Updated background and references.
10/2021	Annual review. Revised coverage rationale to align with NCCN guidelines. Updated background and references.
10/2022	Annual review. Removed coverage for angiosarcoma as no longer recommended by NCCN guidelines. Updated background and references.
10/2023	Annual review. Updated coverage criteria and classifications for CNS Tumor, Melanoma, and Neuroendocrine and Adrenal Tumors per NCCN guidelines. Updated references.
10/2024	Annual review. Updated background to align with new indication. Updated references.

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