

Temodar (temozolomide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Temodar (temozolomide) capsules	May be subject to quantity limit
Temodar (temozolomide) vial	N/A

APPROVAL CRITERIA

Requests for Temodar (temozolomide) may be approved if the following criteria are met:

I. Individual has a diagnosis of one of the following:

A. Bone Cancer – for Ewing Sarcoma (NCCN 2A);

OR

B. Central Nervous System (CNS) Cancers

1. Newly diagnosed for glioblastoma multiforme and using in combination WITH radiotherapy or as maintenance therapy AFTER radiotherapy; **OR**
2. Refractory anaplastic astrocytoma; **OR**
3. Adjuvant treatment of newly diagnosed anaplastic astrocytoma; **OR**
4. Adult glioma (including circumscribed glioma/glioneural tumors, pleomorphic xanthoastrocytoma/glioneuronal tumors, glioblastoma, gliosarcoma, high-grade glioma, astrocytoma, or oligodendroglioma), (NCCN 2A); **OR**
5. Adult intracranial and spinal ependymoma (excluding subependymoma) (NCCN 2A); **OR**
6. Adult medulloblastoma (NCCN 2A); **OR**
7. Primary CNS Lymphoma; **OR**
8. Recurrent or relapsed brain metastases (NCCN 2A); **OR**
9. Initial treatment for small asymptomatic brain metastases (NCCN 2A); **OR**
10. Pediatric diffuse High-Grade gliomas or pediatric diffuse midline glioma, or pediatric medulloblastoma (NCCN 2A, DP BIIa);

OR

C. Cutaneous Melanoma

1. As monotherapy for metastatic or unresectable disease as second-line or subsequent therapy (NCCN 2A)

OR

D. Neuroendocrine Tumors of the Pancreas (NCCN 2A, DP B I);

OR

E. Neuroendocrine Tumors of the Lung and Thymus (Carcinoid Tumors)

1. As treatment for lung/thymic disease (NCCN 2A); **OR**
2. As treatment for poorly controlled carcinoid syndrome if disease in lung/thymus (NCCN 2A);

OR

F. Neuroendocrine and Adrenal Tumors

1. As monotherapy for Pheochromocytoma/Paraganglioma (NCCN 2A); **OR**
2. For poorly differentiated Neuroendocrine Carcinoma/ Large or Small Cell Carcinoma/ Mixed Neuroendocrine - Non-Neuroendocrine Neoplasm (NCCN 2A); **OR**
3. For Well Differentiated Grade 3 neuroendocrine tumors;

OR

G. High-risk Neuroblastoma in combination with irinotecan, dinutuximab, and sargramostim;

OR

H. Mycosis Fungoides/Sézary Syndrome for relapsed/refractory disease with evidence of CNS involvement, as a single agent (NCCN 2A);

OR

I. Primary progressive or relapsed Small Cell Lung Cancer as a single agent (NCCN 2A);

OR

J. Soft Tissue Sarcoma

1. In palliative chemotherapy as a single agent (NCCN 2A); **OR**
2. Nonpleomorphic rhabdomyosarcoma in combination with vincristine and irinotecan (NCCN 2A); **OR**
3. Solitary fibrous tumor in combination with bevacizumab (NCCN 2A);

OR

K. Uterine Neoplasms, for advanced, inoperable, recurrent or metastatic disease as a single agent for second-line or subsequent therapy (NCCN 2A);

OR

L. Uveal Melanoma, for metastatic or unresectable disease as a single agent (NCCN 2A).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: September 17, 2024.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on September 17, 2024.
 - a. Bone Cancer V1.2025. Revised August 20, 2024.
 - b. Central Nervous System Cancers V2.2024. Revised July 25, 2024.

- c. Pediatric Central Nervous System Cancers. V1.2024. Revised February 26, 2024.
- d. Melanoma: Cutaneous V2.2024. Revised April 3, 2024.
- e. Neuroblastoma V2.2024. Revised July 2, 2024.
- f. Neuroendocrine and Adrenal Tumors V2.2024. Revised August 1, 2024.
- g. Primary Cutaneous Lymphomas V3.2024. Revised August 22, 2024.
- h. Small Cell Lung Cancer V2.2025. Revised September 5, 2024.
- i. Soft Tissue Sarcoma V2.2024. Revised July 31, 2024.
- j. Uterine Neoplasms V2.2024. Revised March 6, 2024.
- k. Melanoma: Uveal V1.2024. Revised May 23, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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