

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Temodar (temozolomide)

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

Medications	Line of Business Criteria Applies	Quantity Limit
Temodar (temozolomide) capsules	Commercial, HIX, All MCD	May be subject to quantity limit
Temodar (temozolomide) vial	Commercial, HIX, CCC, AGP, VA MCD	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 and disease has progressed post-chemotherapy with a nitrosourea and procarbazine; **OR**
3. Recurrent or progressive low-grade infiltrative supratentorial astrocytoma/oligodendroglioma, (Label, NCCN 2A); **OR**
4. Anaplastic gliomas (NCCN 2A); **OR**
5. Glioblastomas (NCCN 2A); **OR**
6. Adult intracranial and spinal ependymoma (excluding subependymoma) (NCCN 2A); **OR**
7. Adult medulloblastoma for those with prior chemotherapy (NCCN 2A); **OR**
8. Primary CNS Lymphoma with induction therapy (NCCN 2A); **OR**
9. Primary CNS Lymphoma in relapsed or refractory disease (NCCN 2A); **OR**
10. Recurrent brain metastases in those with stable systemic disease or reasonable systemic treatment options if active against the primary tumor (NCCN 2A);

OR

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C. Lung Neuroendocrine Tumors(NCCN 2A);

OR

D. Cutaneous Melanoma

1. As monotherapy for metastatic or unresectable disease (NCCN 2A); **OR**
2. As monotherapy for disease progression (NCCN 2A);

OR

E. Neuroendocrine Tumors of the Pancreas (NCCN 2A);

OR

F. Neuroendocrine Tumors of the Gastrointestinal Tract, Lung and Thymus (Carcinoid Tumors) (NCCN 2A);

OR

G. Neuroendocrine and Adrenal Tumors

1. As monotherapy for Pheochromocytoma/Paraganglioma with distant metastases (NCCN 2A); **OR**
2. For poorly differentiated (High Grade) Large or Small Cell (NCCN 2A);

OR

H. Mycosis Fungoides/Sézary Syndrome (NCCN 2A); **AND**

I. Relapsed/refractory disease with evidence of CNS involvement;

OR

J. Primary progressive or relapsed Small Cell Lung Cancer (NCCN 2A);

OR

K. Soft Tissue Sarcoma

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

OR

L. Uterine Neoplasms, for recurrent or metastatic disease (NCCN 2A);

OR

M. Uveal Melanoma, for metastatic or unresectable disease (NCCN 2A).

Key References:

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Applicable	X	X	X	X	X	X	X

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 14, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on October 14, 2019.
 - a. Bone Cancer V1.2020. Revised August 12, 2019.
 - b. Central Nervous System Cancers V2.2019. Revised September 16, 2019.
 - c. Cutaneous Melanoma V2.2019. Revised March 12, 2019.
 - d. Neuroendocrine and Adrenal Tumors V1.2019. Revised March 5, 2019.
 - e. Primary Cutaneous Lymphomas V2.2019. Revised December 17, 2018.
 - f. Small Cell Lung Cancer V1.2020. Revised October 10, 2019.
 - g. Soft Tissue Sarcoma V4.2019. Revised September 12, 2019.
 - h. Uterine Neoplasms V4.2019. Revised September 16, 2019.
 - i. Uveal Melanoma V1.2019. Revised June 14, 2019.

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