I. Medication Description

Temozolomide is an oral chemotherapy agent that causes tumor cell death by preventing cell division and cell multiplication. It is not directly active, but undergoes rapid conversion at physiologic pH to a reactive compound (MTIC). The cytotoxicity of MTIC is thought to be primarily due to alkylation of DNA. Alkylation (methylation) occurs mainly at the O\(^6\) and N\(^7\) positions of guanine.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Temodar is available when the following criteria have been met:

- The medication is prescribed by a hematologist/oncologist **AND**
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines\(^\circ\)) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium\(^\circ\)) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Available for dosing as supported by FDA guidelines and Compendia.

V. Coverage Duration

- Astrocytoma/oligodendroglioma, anaplastic astrocytoma and glioblastoma multiforme: 12 months and may be renewed
- All other indications: 6 months and may be renewed

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread **AND**
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

Available as 5mg, 20mg, 100mg, 140mg, 180mg, and 250mg capsules

VIII. Summary of Policy Changes

- 9/1/11: addition of the following diagnoses and criteria for coverage:
  - Primary central nervous system lymphoma
  - Ewing’s sarcoma
  - Metastatic central nervous system lesions (i.e., brain metastases)
  - Mycosis fungoides (MF)/Sezary syndrome (SS)
  - Soft tissue sarcoma
- 9/15/12: Clarification of treatment for astrocytoma and oligodendroglioma; addition of treatment for refractory glioblastoma multiforme; addition of ICD codes 171.4 and 171.6
- 9/15/13: Removal of specific dosing recommendations; Addition of covered indications: medulloblastoma, PNET, neuroendocrine tumors of pancreas, uterine sarcoma, SCLC, lung neuroendocrine tumor
- 9/15/14: updated coverage criteria to match current category 1 and 2A NCCN recommendations
- 7/1/15: formulary distinctions made
- 12/15/15: updated indications to include coverage in DFSP; criteria updated in accordance with current NCCN treatment recommendations
- 9/15/16: policy updated to correspond with current NCCN treatment guidelines
- 10/16/17: coverage criteria updated to allow use as supported by current NCCN guidelines

IX. References

1. UpToDate Online, retrieved April 2011
3. Facts and Comparisons Online, retrieved April 2011

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered. The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.