Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

TEMODAR™ (temozolomide)

GPI CODING:

211040700001**

DESCRIPTION:

Temozolomide is a prodrug that forms a cytotoxic alkylating agent. It is available as an oral and intravenous formulation. At physiologic pH, temozolomide undergoes rapid non-enzymatic conversion to form the active metabolite, monomethyl triazenoimidazole carboxamide (MTIC), the same active compound formed by the metabolism of dacarbazine (DTIC). The cytotoxic effects of MTIC involve alkylation (methylation) of DNA at various sites including the O^6- and N^7-positions on guanine, resulting in inhibition of DNA replication. Temozolomide is cell-cycle non-specific; however, cell cycle arrest usually occurs between G2- and M-phases. The combination of temozolomide and radiation therapy results in additive effects.

APPROVAL DURATION:

Initial approvals and renewals: 12 months.

CRITERIA FOR TEMODAR

I. Patient is ≥18 years of age **AND**
II. Patient has one of the following diagnoses:
   a. Glioblastoma multiforme that is newly diagnosed and temozolomide will be used concomitantly with radiotherapy and then as maintenance treatment **OR**
   b. Refractory anaplastic astrocytoma that progressed on a drug regimen containing nitrosourea or procarbazine **OR**
   c. Off label uses for oncology drugs if considered medically acceptable in one or more of the following compendia (i.e., Micromedex DrugDex, AHFS, Clinical Pharmacology, and NCCN) *A use is identified by a compendium as medically accepted if the:*
      i. *Indication is a Category 1 or 2A in NCCN,*
      ii. *Indication is a Class I, Class IIa or Class IIb in DrugDex,*
      iii. *Narrative text in AHFS or Clinical Pharmacology is supportive; or*
      iv. *The use is supported by clinical research in 2 or more peer-reviewed medical journals*

AND

III. Patient will have an absolute neutrophil count (ANC) performed at baseline and throughout treatment **AND**
IV. *Pneumocystis jiroveci (carinii)* pneumonia (PCP) prophylaxis will be given to patients receiving concomitant temozolomide and radiotherapy for the 42 day regimen for the treatment of newly diagnosed glioblastoma multiforme

Authorization for continued use shall be reviewed at least every 12 months to confirm that current coverage policy criteria are met.