Prior Authorization Conditions for Temodar (temozolomide)

Website form: [www.highmarkhealthoptions.com](http://www.highmarkhealthoptions.com)
Submit request via: Fax- 1-855-476-4158

All requests for Temodar (temozolomide) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

**Temodar (temozolomide) Prior Authorization Criteria:**

- Coverage is provided for the following FDA approved indications:
  - Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment
  - Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine

- **Initial Authorization Criteria:**
  - Patients must be 18 years of age or older
  - The prescribing physician must be an oncologist or hematologist
  - The requested dose and length of therapy prescribed is consistent with FDA approved labeling or peer-reviewed medical literature.
  - Temodar (temozolomide) must be used concomitantly with radiotherapy, starting on the first day of radiotherapy and throughout the entire course of treatment.
  - Newly diagnosed glioblastoma multiforme only: *Pneumocystis* pneumonia (PCP) prophylaxis is required for all patients receiving concomitant Temodar (temozolomide) and radiotherapy for the 42 day regimen
  - Complete blood counts must be obtained weekly throughout the treatment course.
  - Documentation of a hypersensitivity to dacarbazine or any Temodar component

- **Reauthorization Criteria:**
  - Must have documentation and evidence from prescriber indicating no disease progression.

- **Coverage duration:**
  - Authorizations will be issued for 12 months if criteria is met.

- **Recommended dosages:**
  - **Glioblastoma multiforme:**
    - **Concomitant Phase:** 75mg/m² daily for 42 days (maximum of 49 days), starting the first day of radiotherapy.
    - **Maintenance Phase (Initiated 4 weeks after the end of radiotherapy):**
      - Cycle 1: 150mg/m² once daily for 5 days followed by 23 days without treatment.
      - Cycles 2-6: 200mg/m² daily for 5 days followed by 23 days without treatment.
  - **Anaplastic astrocytoma:**
    - Initial dose: 150 mg/m² once daily for 5 consecutive days
    - Next cycle (Day 29, Day 1 of next cycle): May increase dose to 200 mg/m²/day for 5 days consecutive days of a 28- day cycle if ANC and Platelet count are within prescribing limits.

- Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

**References:**
Temodar (temozolomide)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Health Options Pharmacy Services.

FAX: 1-855-476-4158

If needed, you may call to speak to a Pharmacy Services Representative.

PHONE: 1-844-325-6251 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Physician: ____________________________
NPI: ____________________________

Physician Specialty: ____________________________
Office Contact: ____________________________
Office Address: ____________________________
Office Phone: ____________________________
Office Fax: ____________________________

MEMBER INFORMATION

Patient Name: ____________________________
Health Options ID: ____________________________
DOB: ____________________________

Body Surface Area (BSA): ____________________________

DRUG INFORMATION

Medication: ____________________________
Strength: ____________________________
Frequency: ____________________________
Duration: ____________________________

MEDICAL HISTORY

Diagnosis:

☐ Newly diagnosed glioblastoma multiforme (GBM) concomitantly with radiotherapy and then as maintenance treatment

☐ Refractory anaplastic astrocytoma patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine

☐ Other: __________________________________

Is Temodar being used in combination with radiotherapy? ☐ Yes ☐ No

Has the disease progressed while on a drug regimen containing nitrosourea or procarbazine?

☐ Yes ☐ No

Does the patient have newly diagnosed glioblastoma multiforme and receiving Pneumocystis pneumonia (PCP) prophylaxis?

☐ Yes ☐ No

Does the member have a hypersensitivity to dacarbazine or any component of Temodar?

☐ Yes ☐ No

Is the requested dose and length of therapy prescribed consistent with FDA approved labeling or peer-reviewed medical literature?

☐ Yes ☐ No

Please provide pertinent progress notes and lab/radiology reports that describe the member’s current disease status in the supporting information box below for every request.

REAUTHORIZATION:

Is there documentation from the prescriber indicating no disease progression? ☐ Yes ☐ No

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Physician Signature ____________________________ Date ____________________________

6/2017