BlueCross BlueShield of Arizona
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PHARMACY COVERAGE GUIDELINES	**ORIGINAL EFFECTIVE DATE: 3/17/16**
SECTION: DRUGS	**LAST REVIEW DATE: 3/15/18**
	LAST CRITERIA REVISION DATE: 3/15/18
	ARCHIVE DATE:

TEMODAR® (temozolomide) oral capsule
Temozolomide oral capsule

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

Description:

Temodar (temozolomide) is indicated for the treatment of adult patients with newly diagnosed glioblastoma multiforme used concomitantly with radiotherapy and then as maintenance treatment and for the treatment of adult patients with refractory anaplastic astrocytoma in patients who have experienced disease progression on a drug regimen containing nitrosourea and procarbazine.

Temozolomide is not directly active but spontaneously undergoes rapid non-enzymatic conversion at physiologic pH to the reactive compound 5-(3-methyltriazen-1-yl)-imidazole-4-carboxamide (MTIC). MTIC is further hydrolyzed to 5-amino-imidazole-4-carboxamide (AIC), which is known to be an intermediate in purine and nucleic acid biosynthesis, and to methylhydrazine, which is believed to be the active alkylating species. Cytotoxicity is thought to be primarily due to alkylation of DNA. Alkylation (methylation) occurs mainly at the O^6 and N^7 positions of guanine.

Temodar (temozolomide)

Medication class:
Antineoplastic – Imidazotetrazines

FDA-approved indication(s):
For the treatment of adult patients with:
- 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

Recommended Dose:
- Newly Diagnosed GBM:
  - 75 mg/m^2 for 42 days concomitant with focal radiotherapy followed by initial maintenance dose of 150 mg/m^2 once daily for Days 1–5 of a 28-day cycle of Temodar for 6 cycles
    - *Pneumocystis jiroveci* pneumonia (PJP, formerly known as *pneumocystis carinii* pneumonia or PCP) prophylaxis is required for all patients receiving concomitant Temodar and radiotherapy for the 42-day regimen
- Refractory Anaplastic Astrocytoma:
  - Initial dose 150 mg/m^2 once daily for 5 consecutive days per 28-day treatment cycle

Maximum dosage
- Not stated

Available Dosage Forms:
- Capsule: 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, and 250 mg

Warnings, Precautions, and other Clinical Information:
- Dosage must be adjusted according to nadir neutrophil and platelet counts in the previous cycle and the neutrophil and platelet counts at the time of initiating the next cycle

TEMODAR® (temozolomide) oral capsule
Temozolomide oral capsule (cont.)

- Prior to dosing, patients must have an absolute neutrophil count (ANC) greater than or equal to 1.5 × 10^9/L and a platelet count greater than or equal to 100 × 10^9/L
- All patients, particularly those receiving steroids, should be observed closely for the development of lymphopenia and for *Pneumocystis jiroveci* pneumonia (PJP, formerly known as *pneumocystis carinii* pneumonia or PCP)
- Hepatotoxicity – fatal and severe hepatotoxicity have been reported
- Woman patient of child bearing potential should be warned against becoming pregnant
- Woman patient who is breast feeding an infant or child should stop breast feeding
- Male patient with female partner of reproductive potential should use effective contraception
- Male patient who has a female partner of child bearing potential should be warned against becoming pregnant

Criteria:

- **Criteria for initial therapy**: Temodar (temozolomide) and generic temozolomide is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is an Oncologist

2. Individual is 18 years of age or older

3. A confirmed diagnosis of **ONE** of the following:
   - Newly diagnosed glioblastoma multiforme (GBM) used concomitantly with radiotherapy **and** concurrent prophylaxis for *Pneumocystis jiroveci* pneumonia (PJP, formerly known as *pneumocystis carinii* pneumonia or PCP)
   - Maintenance treatment GBM
   - Refractory anaplastic astrocytoma patient who has experienced disease progression on a drug regimen containing nitrosourea and procarbazine (Matulane)

4. **ALL** of the following baseline tests have been completed before initiation of treatment:
   - Complete blood count (CBC) with differential
   - Liver function tests

5. There are **NO** contraindications:
   - Contraindications include:
     - Known hypersensitivity to any temozolomide component
     - Patients who have a history of hypersensitivity to dacarbazine (DTIC)

Initial approval duration: 6 months

TEMODAR® (temozolomide) oral capsule
Temozolomide oral capsule (cont.)

- **Criteria for continuation of coverage (renewal request):** Temodar (temozolomide) and generic temozolomide is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Individual continues to be in consultation with an Oncologist
  2. Individual's condition has not worsened while on therapy
  3. Individual has been adherent with the medication
  4. Individual has not developed any contraindications or other significant level 4 adverse drug effects that may exclude continued use
     - Contraindications as listed in the criteria for initial therapy section
     - Significant adverse effect such as:
       - Neutropenia or thrombocytopenia
       - Hepatotoxicity
  5. There are no significant interacting drugs

  Renewal duration: 6 months

Resources:

Off Label Use of Cancer Medications: A.R.S. §§ 20-826(R) & (S). Subscription contracts; definitions.

Off Label Use of Cancer Medications: A.R.S. §§ 20-1057(V) & (W). Evidence of coverage by health care service organizations; renewability; definitions.

Temodar. Package Insert. Revised by manufacturer 10/2017. Accessed 02-27-18.

Temodar. Package Insert. Revised by manufacturer 09/2015. Accessed 03-17-16, 02-14-17.

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Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

Pharmacy Prior Authorization Request Form

Do not copy for future use. Forms are updated frequently.
REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.

Member Information

Member Name (first & last):	Date of Birth:	Gender:	BCBSAZ ID#:
Address:	City:	State:	Zip Code:

Prescribing Provider Information

Provider Name (first & last):	Specialty:	NPI#:	DEA#:
Office Address:	City:	State:	Zip Code:
Office Contact:	Office Phone:	Office Fax:	

Dispensing Pharmacy Information

Pharmacy Name:	Pharmacy Phone:	Pharmacy Fax:

Requested Medication Information

Medication Name:	Strength:	Dosage Form:
Directions for Use:	Quantity: / Refills:	Duration of Therapy/Use:

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

Clinical Information

1. **What is the diagnosis? Please specify below.**

   ICD-10 Code: _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

Medication Name, Strength, Frequency	Dates started and stopped or Approximate Duration	Describe response, reason for failure, or allergy

5. **Are there any supporting labs or test results? Please specify below.**

Date	Test	Value

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Pharmacy Prior Authorization Request Form

6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider's Signature: Date:

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.