BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

Temozolomide oral capsule

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for Temozolomide

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a physician specializing in the diagnosis or in consultation with an Oncologist

Indication
- Newly diagnosed glioblastoma used with radiotherapy and then as maintenance treatment
- Adjunctive treatment in newly diagnosed anaplastic astrocytoma
- Treatment of refractory anaplastic astrocytoma
- Other oncologic direct treatment uses listed in the National Comprehensive Cancer Network (NCCN) Guidelines with Categories of Evidence and Consensus of 1 and 2A

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Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Complete blood count with differential
- Absolute neutrophil count is 1.5 x 10^9/L or greater
- Platelet count is 100 x 10^9/L or greater
- Liver function tests
- Negative pregnancy test in a woman of childbearing potential

Safety
- No history of hypersensitivity to dacarbazine (DTIC)

Additional Requirements
- No severe renal impairment (creatinine clearance less than 36 mL/min/m^2) or end stage renal disease on dialysis
- No severe hepatic impairment (Child Pugh Class C)

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results (CBC with differential, ANC, platelet count, liver function tests, pregnancy test)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by a physician specializing in or is in consultation with an Oncologist

Clinical Response
- Documented evidence of efficacy, disease stability, and/or improvement
- No significant unacceptable adverse drug reactions

Adherence
- Adherence to the prescribed therapy regimen has been documented

Safety
- No new contraindications
- No significant adverse effects such as:
  - Severe myelosuppression (e.g., pancytopenia, leukopenia, neutropenia, thrombocytopenia, anemia)
  - Severe hepatotoxicity
  - Pneumocystis Pneumonia (PCP)

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Additional Requirements

- No severe renal impairment (creatinine clearance less than 36 mL/min/m²) or end stage renal disease on dialysis
- No severe hepatic impairment (Child Class C)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement in given indication
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

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.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

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Resources:

Temozolomide cap product information, revised by Accord Healthcare Inc. 06-2024. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 24, 2025.

National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Central Nervous System Cancers Version 2.2025 – Updated August 28, 2025. Available at https://www.nccn.org. Accessed November 10, 2025.

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.

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