Washington State Health Care Authority

Antineoplastics and Adjunctive Therapies - Imidazotetrazines – Oral

Medical policy no. 21.10.40 Effective Date: TBD

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Background:

The antineoplastics and adjunctive therapies are classes of medications used for the treatment of cancer and cancer-related conditions.

Medical necessity:

Drug	Medical Necessity
Temozolomide **(TEMODAR)**	Temozolomide may be considered medically necessary when used for: 1. conditions listed under Indications and Usage in approved drug labeling (prescribing information) from the Food and Drug Administration (FDA); **OR** 2. conditions listed as medically-accepted indications in any of the compendia of drug information recognized by Medicaid

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Temozolomide **(TEMODAR)**	Temozolomide may be covered when all the following criteria are met: 1. Patient has a diagnosis and staging of a cancer that: a. the requested medication is indicated for and is supported in one of the following: i. listed in the approved drug labeling (prescribing information); **OR** ii. listed as a medically-accepted indication in compendia recognized by Medicaid; **AND** b. if the requested medication is to be used in combination with other chemotherapeutic or adjuvant therapies, then documentation of the entire chemotherapy regimen is required; **AND**

c. if the requested medication is not indicated as a first line agent, then documentation of all previous therapies tried and failed, the duration, and reasons for stopping the therapy are required;
    i. if the agent was stopped for lack of benefit, documentation of what measures were used to define positive clinical response and what was the change at end of therapy from baseline;

2. Patient has received tests that confirm the diagnosis and staging including but not limited to:
    a. if an FDA-approved companion diagnostic test exists for the requested agent, then documentation that the test(s) were performed to confirm the diagnosis is required
    b. if a medically necessary test with adequate ability to confirm a gene-mutation exists, then documentation that the test(s) were performed to confirm the mutation as part of the diagnosis is required
    c. if any other companion tests have been used for concurrent or previous treatments, the documentation that the test(s) were performed is required; **AND**
3. The requested medication is prescribed by, or in consultation with, a specialist in oncology or neurology; **AND**
4. The patient does not have any contraindications to the requested medication or any other medications as part of the regimen; **AND**
5. The prescribed quantity and dosing regimen for the patient's age and other factors is within the manufacturer's published dosing guidelines or compendia recognized by Medicaid; **AND**
6. Documentation from the provider on how they will monitor and measure the patient and their condition to determine tolerability and patient-specific positive clinical response

If ALL criteria are met, the request will be approved for 6 months.

If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.

Criteria (Reauthorization)

Temozolomide may be reauthorized when all the following criteria are met:

1. Documentation of the change from baseline of the measures used to determine tolerability and patient specific positive clinical response; **AND**

	2. If the requested medication is to be used in combination with other chemotherapeutic or adjuvant agents according to the approved drug labeling or medically-accepted indication, then documentation of all other appropriate chemotherapy agents, including those concurrently requested, for this regimen is required **If ALL criteria are met, the request will be approved for 6 months.** If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.

Dosage and quantity limits:

Drug Name	Dose and Quantity Limits
Temozolomide **(TEMODAR)**	Astrocytoma – Initial: 150mg/m^2 per day for 5 days of a 28 day cycle Astrocytoma – Maintenance: Up to 200mg/m^2 for 5 days of a 28 day cycle Glioblastoma – Initial: 75mg/m2 per day up to 49 days Glioblastoma – Maintenance, cycle 1: 150mg/m^2 for 5 days of a 28 day cycle Glioblastoma – Maintenance, cycles 2 to 6: Up to 200mg/m2 per day for 5 days of a 28 day cycle

Coding:

HCPCS Code	Description
J8700	Temozolomide, oral, 5 mg
J9328	Temozolomide, injection, 1 mg

References

1. Temodar [package insert]. Whitehouse Station, NJ; Merck; November 2017.

History:

Date	Action and Summary of Changes
01.20.2021	Updating policy
07.25.2019	Formatting change
07.01.2019	New Policy

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Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No
   If yes, is there documentation of a positive clinical response? ☐ Yes ☐ No

2. What is the patient's diagnosis (ICD code plus description)?
   Indicate stage:
   Indicate disease type:

3. Is this being used in combination with other chemotherapeutic or adjuvant agents? ☐ Yes ☐ No
   If yes, list all therapies:

4. List treatments patient has previously tried and dates these treatments were started:
   How long was the patient on these treatments?
   Why were they stopped or discontinued?

5. Has the diagnosis and disease mutation been confirmed with an FDA approved companion diagnostic test?
   ☐ Yes ☐ No
   Attach labs and results of all diagnostic tests performed to confirm diagnosis.

6. Is there a contraindication to the requested medication or any other medications that are part of the patient's regimen? ☐ Yes ☐ No
   If yes, indicate contraindication(s):

7. What is the patient's planned dosing regimen?

8. Has this medication been prescribed by, or in consultation with a specialist in oncology or neurology?
   ☐ Yes ☐ No

9. Indicate for patient:
   Height (cm): **Date taken:**
   Weight (kg): **Date taken:**
   Body surface area (m^2): **Date taken:**

CHART NOTES, LABS AND RESULTS OF DIAGNOSTIC TESTS ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date