Oncology Agents: Antimetabolites - Oral

WA.PHAR.157 Effective Date: 8/1/2026

Related medical policies:

Policy Name
N/A

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 publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: *https://www.coordinatedcarehealth.com/providers/pharmacy.html*

Medical necessity

Drug	Medical Necessity
azacitidine (Onureg) thioguanine (Tabloid)	**Oncology Agents: Antimetabolites - Oral** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. • Non-Preferred brand name products on the Apple Health Drug List with an A-rated generic, biosimilar or interchangeable biosimilar must also meet criteria in the WA.PHAR.65 Brands with Biosimilars or A-rated Generic policy. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

Clinical policy:

Clinical Criteria	
Acute myeloid leukemia azacitadine (Onureg) thioguanine (Tabloid)	Azacitadine (Onureg) or thioguanine (Tabloid) may be approved when all of the following documented criteria are met: 1. Patient meets one of the age criteria: a. For azacitadine, 18 years of age or older; **OR** b. For thioguanine, there is no age requirement; **AND**

	2. Prescribed by, or in consultation with, an oncologist or hematologist; **AND** 3. Diagnosis of acute myeloid leukemia; **AND** 4. Patient is being prescribed therapy for one of the following: a. For azacitadine: i. The patient is receiving continued treatment after achieving first complete remission; **OR** ii. The patient has achieved complete remission with incomplete blood count recovery following intensive induction chemotherapy and are unable to complete intensive curative therapy; **OR** b. For thioguanine: The patient is receiving therapy for induction or consolidation therapy. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Azacitadine (Onureg) or thioguanine (Tabloid) may be approved when all the following documented criteria are met: 1. Documentation is submitted demonstrating disease stability or a positive clinical response [e.g., patient remains in remission, stabilization of disease, lack of disease progression]. If ALL criteria are met, the request will be authorized for **6 months.**

Dosage and quantity limits

Drug	Indication	Approved Dose	Dosage Form and Quantity Limit
Onureg	Acute myeloid leukemia	300 mg once daily, on days 1 through 14 of each 28-day cycle	• 200 mg tablets: 14 tablets per 28 days • 300 mg tablets: 14 tablets per 28 days
Tabloid	Acute myeloid leukemia	Up to 3 mg/kg per day.	• 40 mg tablets: Weight-based

Coding:

HCPCS Code	Description
N/A	N/A

Background:

The safety and efficacy of Onureg was established in a randomized, double-blind, placebo-controlled clinical trial with 472 participants. Participants had acute myeloid leukemia (AML) and were randomized to Onureg or placebo after achieving complete remission or complete remission with incomplete blood count recovery with induction chemotherapy. The primary endpoint was overall survival. The median overall survival was significant between the Onureg and placebo groups, 24.7 months and 14.8 months, respectively. For safety, 15% of participants who received Onureg experienced serious adverse reactions. The more common (2% or more) serious adverse effects include pneumonia (8%) and febrile neutropenia (7%). The most common (10% or more) adverse effects includes nausea, vomiting, diarrhea, fatigue/asthenia, constipation, pneumonia, abdominal pain, arthralgia, decreased appetite, febrile neutropenia, dizziness and pain in extremity.[1]

The safety and efficacy of Tabloid was established in two studies. For the pediatric population, 69 of 163 (59%) pediatric participants who were previously untreated for acute nonlymphocytic leukemia obtained complete remission. The median duration of remission was 11.5 months. For the adult population, 53% of adult participants, previously untreated for acute nonlymphocytic leukemia, obtained remission. The median duration of remission was 8.8 months. For safety, the most frequent adverse effect is myelosuppression. Frequent adverse effects include hyperuricemia and less frequent adverse effects include nausea, vomiting, anorexia, and stomatitis. The long-term use of thioguanine is not recommended as it has been reported to cause liver toxicity with vascular endothelial damage.

References

1. Onureg [Prescribing Information]. Summit, NJ: Celgene Corporation. May 2021.
2. Tabloid [Prescribing Information]. Wixom, MI: Waylis Therapeutics LLC. July 2024.

History

Approved Date	Effective Date	Version	Action and Summary of Changes
02/18/2026	08/01/2026	21.30.00-1	New policy created