

Pharmacy Policy

Onureg

Policy Number: 9.722

Version Number: 1.0

Version Effective Date: 9/1/2021

Product Applicability <input type="checkbox"/> All Plan⁺ Products	
Well Sense Health Plan	Boston Medical Center HealthNet Plan
<input type="checkbox"/> New Hampshire Medicaid	<input type="checkbox"/> MassHealth - MCO
	<input type="checkbox"/> MassHealth - ACO
	<input checked="" type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct
	<input type="checkbox"/> Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- **Onureg (azacitidine tablets)**

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	<ol style="list-style-type: none"> 1. Prescribed in combination with venetoclax for AML as replacement for IV azacitidine. OR 2. Members with a diagnosis of MDS as a “replacement for IV azacitidine”.
Required	<ol style="list-style-type: none"> 1. Diagnosis of Acute Myeloid Leukemia. AND

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Medical Information	<p>2. Member is 18 years of age or older. AND</p> <p>3. Achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy. AND</p> <p>4. Member is not able to complete intensive curative therapy (allogeneic HCT) AND</p> <p>5. A 21 day dosing schedule may be allowed for patients who experience AML relapse with 5% of 15% of blasts in blood or bone marrow.</p>
Age Restriction	18 years of age
Prescriber Restriction	Prescribed by or in consultation with an Oncologist.
Coverage Duration	12 months
Other criteria	None

Clinical Background Information and References

1. Onureg (azacitidine) [prescribing information]. Summit, NJ: Celgene Corporation; March 2021.
2. UpToDate. Azacitidine Drug information. Topic 8797 Version 285.0. Accessed March 2021.
3. Wei AW, Döhner H, Pocock C, et al; QUAZAR AML-001 Trial Investigators. Oral azacitidine maintenance therapy for acute myeloid leukemia in first remission. N Engl J Med. 2020;383(26):2526-2537. doi:10.1056/NEJMoa2004444 [PubMed 33369355].

Original Approval Date	Original Effective Date	Policy Owner	Approved by
5/13/2021	9/1/2021	Pharmacy Department	P&T Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
5/13/2021	Policy created	9/1/2021	P&T Committee

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Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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