Onureg (azacitidine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Onureg (azacitidine)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Onureg (azacitidine) may be approved if the following criteria are met:

I. Individual has a diagnosis of acute myeloid leukemia (AML), including de novo AML and AML secondary to prior myelodysplastic disease or chronic myelomonocytic leukemia (NCT01757535); **AND**
   A. Individual has achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy; **AND**
   B. Individual is unable to complete intensive curative therapy (e.g. allogeneic hematopoietic stem cell transplant); **AND**
   C. Onureg is used as a single agent.

OR

II. Individual has a diagnosis of relapsed or refractory Peripheral T-Cell Lymphomas (including angioimmunoblastic T-cell lymphoma (AITL), nodal peripheral T-cell lymphoma with TFH phenotype (PTCL, TFH), and follicular T-cell lymphoma (FTCL) (NCCN 2A); **AND**
   A. Individual is using as second-line or subsequent therapy; **AND**
   B. Onureg is used as a single agent.

Requests for Onureg (azacitidine) may not be approved for the following:

I. Individual has a current diagnosis of myelodysplastic syndrome; **OR**
II. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. Clinicaltrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US) 2000 Feb 29- . Identifier NCT01757535. Efficacy of Oral Azacitidine Plus Best Supportive Care as Maintenance Therapy in Subjects With Acute Myeloid Leukemia in Complete Remission (QUAZAR AML-001): 2019 Oct 24 [cited 2020 Sept 10]. Available from: https://clinicaltrials.gov/ct2/show/NCT01757535. .

3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Dupuis J, Tsukasaki K, Bachy E, et al. Oral azacytidine in patients with relapsed/refractory angioimmunoblastic T-cell lymphoma: Final analysis of the Oracle phase III study [abstract]. Blood 2022;140(suppl 1):2310-2312.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on January 17, 2024.
    a. Acute Myeloid Leukemia. V6.2023. Revised October 24, 2023.
    b. T-Cell Lymphomas. V1.2024. Revised December 21, 2023.
8. Ruan J, Moskowitz AJ, Mehta-Shah N, et al. Multi-Center Phase II Study of Oral Azacitidine (CC-486) Plus CHOP As Initial Treatment for Peripheral T-Cell Lymphoma (PTCL) [abstract]. Blood 2020;136:33-34. Available at: https://doi.org/10.1182/blood-2020-136023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.