Clinical Policy Title:	azacitidine
Policy Number:	RxA.549
Drug(s) Applied:	azacitidine, Vidaza®, Onureg®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Myelodysplastic Syndromes (MDS) (must meet all)**:**

1. Diagnosis of MDS;
2. Request is for Vidaza®.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Juvenile Myelomonocytic Leukemia (JMML) (must meet all):

1. Diagnosis of JMML;
2. Request is for Vidaza®.

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Acute Myeloid Leukemia (AML) (Vidaza off-label) (must meet all):

1. Diagnosis of AML;
2. For Onureg® requests, member meets all of the following (a, b, c and d):
   a. Request is for maintenance therapy;
   b. Request is for a single-agent therapy;
   c. Member achieved CR or CRi following intensive induction chemotherapy and is not able to complete intensive consolidation/curative therapy;
   d. Medical justification supports inability to use Subcutaneous/Intravenous azacitidine (e.g., contraindication to excipients).

Approval Duration

All Lines of Business (except Medicare): 6 months

D. Myelofibrosis (MF) (off-label) (must meet all):

1. Diagnosis of advanced phase (i.e., accelerated- or blast-phase) myelofibrosis (MF);
2. Request is for Vidaza®.

Approval Duration

All Lines of Business (except Medicare): 6 months

E. Myelodysplastic syndrome (MDS) / Myeloproliferative Neoplasms (MPN) Overlap Neoplasms (must meet all):

1. Request is for the treatment of one of the following (a, b, c, d, or e):
   a. Chronic myelomonocytic leukemia (CMML)-1 as a single agent;
   b. CMML-2 as a single agent or in combination with ruxolitinib;
   c. BCR-ABL negative atypical chronic myeloid leukemia (aCML) as a single agent or in combination with ruxolitinib;
   d. Unclassifiable MDS/MPN ("overlap syndrome") as a single agent;
   e. MDS/MPN with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T) as a single agent or in combination with lenalidomide.
2. Request is for Vidaza®.

Approval Duration
All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Myelodysplastic Syndromes Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2024. Available at http://www.nccn.org/professionals/physician_gls/pdf/aml.pdf Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Myeloproliferative Neoplasms Version 2.2024. Available at https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed 1. Clinical Policy title was updated to “azacitidine”. 2. Line of business policy applies to was updated to “All lines of business”. 3. HIM approval duration removed & updated. 4. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 5. References were reviewed and updated.	09/18/2020	12/07/2020
Policy was reviewed 1. Clinical Policy Title Drugs Applied was updated to include Onureg®.	09/28/2021	12/07/2021

2. Initial Approval Criteria I.B & I.B.1 was updated to include off-label diagnosis "Myelofibrosis" & "Advanced phase (i.e., accelerated- or blast-phase....." respectively. 3. Initial Approval Criteria I.B.4.b.iii & I.B.4.d was updated to include "In combination with Venclexta®". 4. Initial Approval Criteria I.B.4.d was updated to include "Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm...". 5. Initial Approval Criteria I.C was updated to include off-label indications "Myelodysplastic syndrome (MDS) / Myeloprolif erative Neoplasms (MPN) Overlap Neoplasms". 6. References were reviewed and updated.		
Policy was reviewed 1. Initial Approval Criteria, I.A.2 and I.E.3: Updated to include new drug request criteria Request is for Vidaza®. 2. Initial Approval Criteria, I.A.4: Updated to remove prior criteria pertaining to indication MDS "Member meets one of the following (a, b, c, d, or e): a. With del(5q) cytogenetic abnormality: Failure of Revlimid® at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization may be required for Revlimid® b. Without del(5q) cytogenetic abnormality and serum erythropoietin ≤ 500 mU/mL: Failure of Revlimid® and one of the following agents, unless all are contraindicated or clinically significant adverse effects are experienced: epoetin alfa (e.g., Epogen®, Procrit®, Retacrit™), Aranesp®; *Prior authorization may be required for Revlimid®, epoetin alfa (e.g., Epogen®, Procrit®, Retacrit™), and Aranesp®; c. Has previously received stem cell transplantation, will be receiving azacitidine as a bridge while awaiting stem cell transplant donor availability, or is not a candidate for stem cell transplant.	09/19/2022	10/19/2022

d. Without del(5q) cytogenetic abnormality and serum erythropoietin > 500 mU/mL 3. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, JMML. 4. Initial Approval Criteria, I.C.5 Updated to remove prior prescribing criteria "For Vidaza® requests, prescribed for one of the following (a, b, c or d):* a. In members age ≥ 60 years for one of the following (i, ii, or iii): i. As a single agent; ii. In combination with Nexavar® for FLT3-ITD mutation-positive disease; iii. In combination with Venclexta®; b. Relapsed/refractory disease for one of the following (i, ii, iii or iv): i. As a component of repeating the initial successful induction regimen if late relapse (≥ 12 months); ii. As a single agent; iii. In combination with Venclexta®; iv. In combination with Nexavar® for FLT3-ITD mutation-positive disease; c. Treatment of myelofibrosis (MF)-accelerated phase or MF-blast phase/acute myeloid leukemia; d. Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) in combination with Venclexta®. *Prior authorization may be required for Nexavar® and Venclexta®." 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Added generic azacitidine to Drug(s) Applied. 2. Removed age restrictions. 3. Removed prescriber restrictions. 4. Removed dose restrictions. 5. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 6. Removed reauthorization requirement for positive response to therapy. 7. Updated approval duration verbiage. 8. References were reviewed and updated.	8/28/2024	9/13/2024