Clinical Policy Title:	decitabine/cedazuridine
Policy Number:	RxA.645
Drug(s) Applied:	Inqovi®
Original Policy Date:	03/06/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Myelodysplastic Syndromes (must meet all):

1. Diagnosis of MDS.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia (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 Guidelines. Myelodysplastic Syndromes Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed August 28, 2024.
2. M.D. Anderson Cancer Center. Phase I Study of Ruxolitinib for Patients with Low or Intermediate-1 Risk Myelodysplastic Syndrome (MDS). clinicaltrials.gov; 2019. Available at: https://clinicaltrials.gov/ct2/show/NCT01895842. Accessed August 28, 2024.
3. The International Prognostic Scoring System. Myelodysplastic Syndromes. Leukemia & Lymphoma Society. Available at: https://www.lls.org/myelodysplastic-syndromes/diagnosis/international-prognostic-scoring-system. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/27/2020	09/14/2020
Policy was reviewed: 1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	07/08/2021	09/14/2021

Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new trial and failure criteria – "Trial and failure of decitabine (Dacogen®)…". 2. References were reviewed and updated.	06/30/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A: Updated indication title from Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia to Myelodysplastic Syndromes. 2. Initial Approval Criteria, I.A.1: Updated diagnostic criteria to remove "CMML". 3. Initial Approval Criteria, I.A.2: Updated prescriber criteria to include Hematologist. 4. Initial Approval Criteria, I.A.4: Updated to remove prior trial and failure criteria "Trial and failure of decitabine (Dacogen®) or azacitidine (Vidaza®), unless contraindicated or clinically significant adverse effects are experienced; *Prior authorization may be required for decitabine and azacitidine." 5. References were reviewed and updated.	05/01/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024