

<b>Clinical Policy Title:</b>	decitabine/cedazuridine
<b>Policy Number:</b>	RxA.645
<b>Drug(s) Applied:</b>	Inqovi®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	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](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: <ol style="list-style-type: none"> <li>1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>2. References were reviewed and updated.</li> </ol>	07/08/2021	09/14/2021

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.4: Updated to include new trial and failure criteria – “Trial and failure of decitabine (Dacogen®)...”.</li> <li>2. References were reviewed and updated.</li> </ol>	06/30/2022	07/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A: Updated indication title from Myelodysplastic Syndromes and Chronic Myelomonocytic Leukemia to Myelodysplastic Syndromes.</li> <li>2. Initial Approval Criteria, I.A.1: Updated diagnostic criteria to remove "CMML".</li> <li>3. Initial Approval Criteria, I.A.2: Updated prescriber criteria to include Hematologist.</li> <li>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.”</li> <li>5. References were reviewed and updated.</li> </ol>	05/01/2023	07/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed age restrictions.</li> <li>2. Removed prescriber restrictions.</li> <li>3. Removed dose restrictions.</li> <li>4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days.</li> <li>5. Removed reauthorization requirement for positive response to therapy.</li> <li>6. Updated approval duration verbiage.</li> <li>7. References were reviewed and updated.</li> </ol>	8/28/2024	9/13/2024
<p>Policy was reviewed.</p>	12/05/2024	N/A
<p>Policy reviewed.</p>	12/11/2025	12/11/2025