Generic Name: Decitabine and cedazuridine

Therapeutic Class or Brand Name: Inqovi

Applicable Drugs (if Therapeutic Class): N/A

Preferred: Decitabine inj. (generic)

Non-preferred: Inqovi

Date of Origin: 2/26/2021

Date Last Reviewed / Revised: 2/24/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

I. Documented diagnosis of myelodysplastic syndromes (MDS) and meets the following (A and B):
   A. Previously treated and untreated, de novo and secondary MDS with ONE of the following French-American-British subtypes:
      1. Refractory anemia
      2. Refractory anemia with ringed sideroblasts
      3. Refractory anemia with excess blasts
      4. Chronic myelomonocytic leukemia [CMML]
   B. Documented intermediate-1, intermediate-2, OR high-risk International Prognostic Scoring System group (IPSS).

II. Documented treatment failure, intolerance, or contraindication to hypomethylating agents, such as azacitidine IV/SQ (generic) or decitabine IV (generic).

III. Minimum age requirement: 18 years old

IV. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VI. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A.

OTHER CRITERIA

- Myelosuppression: Fatal and serious myelosuppression and infectious complications can occur. Obtain complete blood cell counts prior to initiation of INQOVI, prior to each cycle, and as clinically indicated to monitor for response and toxicity. Delay the next cycle and resume at the same or reduced dose as recommended.

- Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of reproductive potential of the potential risk to a fetus and to use effective contraception.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Decitabine 35 mg/cedazuridine 100 mg tablets: Up to 5 tablets per 28 days.

APPROVAL LENGTH

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Inqovi. Prescribing information. Taiho Oncology, Inc; March 2022. Accessed January 8, 2025. https://taihocorp-media-release.s3.us-west-2.amazonaws.com/documents/INQOVI_Prescribing_Information.pdf
2. The National Comprehensive Cancer Network (NCCN). Myelodysplastic Syndromes. Version 1.2025. Accessed January 8, 2025. https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf