

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:** 2/17/2023

PRIOR AUTHORIZATION CRITERIA

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

- I. Documented diagnosis of myelodysplastic syndromes (MDS) including previously treated and untreated, de novo and secondary MDS with the following French-American-British subtypes: refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia [CMML].
- II. International Prognostic Scoring System: intermediate-1, intermediate-2, or high-risk.
- III. History of clinically significant treatment failure, intolerance, or contraindication to hypomethylating agents, such as azacitidine IV/SQ (generic) or decitabine IV (generic).
- IV. Age \geq 18 years old.
- V. Prescribed by or in consultation with an oncologist or hematologist.
- VI. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

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:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective for patient's condition.

APPENDIX

- N/A

REFERENCES

1. Inqovi[®] (Decitabine and cedazuridine). Prescribing Information. Princeton, NK; Taiho Oncology. March 2022. Accessed February 17, 2023.
https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf.
2. NCCN Guidelines. Myelodysplastic Syndromes (Version 1.2023).
www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed February 17, 2023.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.