

Generic Name: Decitabine and Cedazuridine

Therapeutic Class or Brand Name: Inqovi[®]

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 21990002250320

Preferred: N/A

Non-preferred: N/A

Date of Origin: 12/14/2020

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - IV 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. Age \geq 18 years old.
- IV. Prescribed by or in consultation with an oncologist.

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® (Decitabine and cedazuridine) [package insert]. Princeton, NJ: Taiho Oncology, Inc; July 2020. Available at:
https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/212576s000lbl.pdf.
2. Medispan.
3. The National Comprehensive Cancer Network (NCCN) Guidelines Version 2.2021 for Myelodysplastic Syndromes (MDS)
https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf

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.