

## Decitabine and cedazuridine (INQOVI) December 2021

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or [PBM INTRANet](#) for further information.

### Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive decitabine and cedazuridine.

- Any hypersensitivity reaction to azacitidine, decitabine or cedazuridine
- Previous use of at least four cycles of decitabine IV or azacitidine without clinical response or benefit
- Concurrent treatment with lenalidomide, injectable azacitidine or injectable decitabine
- Renal dysfunction – Creatinine Clearance <30 mL/min (for Creatinine Clearance 30 – 59 mL/min monitor frequently for adverse reactions)
- Hepatic dysfunction – AST/ALT  $\geq$  2.5 x upper limit of normal (ULN), Bilirubin  $\geq$  2 x ULN
- Pregnancy (i.e. known pregnancy or positive pregnancy test)
- Breastfeeding

### Inclusion Criteria

All of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA/VA Community Care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status of 0 – 2
- Goals of care and role of Palliative Care consult have been discussed and documented
- Patients of child-bearing potential and patients with partners of child-bearing potential: counseling provided on contraception and risks vs. benefits of treatment. Use effective contraception during therapy and for 6 months after the last dose.

### Additional Inclusion Criteria

All of the following must be fulfilled in order to meet criteria:

- Diagnosis of myelodysplastic syndrome (MDS), including previously treated or untreated, de novo and secondary MDS (RA, RA-RS, RA-EB and CMML)<sup>^</sup> and intermediate-1, intermediate-2, and high-Risk IPSS-R groups
- Parenteral therapy refused by patient or impractical (due to travel or healthcare setting exposure risk)

<sup>^</sup> Refractory anemia (RA), refractory anemia with ringed sideroblasts (RA-RS), refractory anemia with excess blasts (RA-EB), and chronic myelomonocytic leukemia (CMML)

## Supplemental Information

Parenteral decitabine represents a substantial cost savings when compared to oral decitabine and cedazuridine. This financial savings in drug cost needs to be balanced against decreased convenience and increased healthcare facility exposure associated with parenteral decitabine administration. Utilization of decitabine and cedazuridine may offer the ability for patients to continue to be cared for by VA Oncology services and avoid referrals for community-based care. Practitioners are encouraged to be mindful of these considerations when deciding between the use of IV decitabine or decitabine and cedazuridine.

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