Azacitidine Oral (ONUREG®)
Criteria for Use
January 2022

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 the *PBM INTERnet* or *PBM INTRAnet* site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive oral azacitidine

- ☐ Using oral azacitidine as a substitute for parenteral azacitidine, as oral and IV formulations of azacitidine are **not interchangeable**
- ☐ Using oral azacitidine to treat myelodysplastic syndrome (MDS)
- ☐ Patient with secondary Acute Myeloid Leukemia (AML) who previously received treatment with a hypomethylating agent (i.e. for MDS)
- ☐ History of hypersensitivity to azacitidine or mannitol
- ☐ Inability to swallow whole tablets
- ☐ Baseline Absolute Neutrophil Count < $0.5x10^9$/L and Platelets < $20x10^9$/L
- ☐ Renal insufficiency (i.e., SCr > 2.5 x Upper Level of Normal (ULN))
- ☐ Hepatic insufficiency (i.e., total bilirubin > 1.5 x ULN, AST and ALT > 2.5 x ULN)
- ☐ Pregnancy (i.e., known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

Inclusion Criteria

The answers to all must be fulfilled in order to meet criteria

- ☐ Care provided by a VA/VA Community Care hematology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group Performance Status 0 to 3

Additional Inclusion Criteria

- ☐ Age $\geq$ 55 with newly diagnosed de novo or secondary AML
- ☐ Patient achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy
- ☐ Patient is not a candidate or is unable to complete intensive curative therapy (i.e. consolidation therapy, candidate for allogeneic hematopoietic stem cell transplant)