Olutasidenib (REZLIDHIA)
Criteria for Use
August 2023

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 olutasidenib.

- ☐ Severe renal impairment (defined as CrCl < 30 ml/min)
- ☐ Severe hepatic impairment (defined as total bilirubin > 3x Upper limit of normal and any AST)
- ☐ Chronic or unresolved infection
- ☐ Unmanageable drug interaction
- ☐ Pregnancy
- ☐ Breastfeeding

Inclusion Criteria

The answers to all of the following must be fulfilled in order to meet criteria.

- ☐ Care provided by a VA/VA Community Care hematology/oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ ECOG performance status 0-2
- ☐ Presence of an isocitrate dehydrogenase-1 (*IDH-1*) mutation
- ☐ Diagnosis of relapsed or refractory acute myeloid leukemia

For women of childbearing potential

- ☐ Pregnancy should be excluded prior to receiving olutasidenib and the patient provided contraceptive counseling on potential risks vs. benefits of taking olutasidenib if patient were to become pregnant.
- ☐ Advise women not to breastfeed during treatment with olutasidenib and for at least 2 weeks after the last dose.

July 2023. Contact: Berni Heron, Pharm.D., BCOP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services