Ivosidenib (TIBSOVO)
Criteria for Use
March 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 ivosidenib.

- ☐ Inability to swallow whole tablets
- ☐ Severe renal impairment (defined as CrCl < 30 ml/min)
- ☐ Severe hepatic impairment (defined as Child-Pugh C)
- ☐ Baseline QTc ≥ 450 msec and/or history of long QT syndrome
- ☐ Clinically significant cardiovascular disease such as uncontrolled or symptomatic arrhythmias, CHF (NYHA Class 3 or 4) or myocardial infarction in prior 6 months
- ☐ Unmanageable CYP3A4 inducer/inhibitor and/or QTc-prolonging drug interaction identified
- ☐ Chronic or unresolved infection
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ 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

For patients of childbearing potential

- ☐ Pregnancy should be excluded prior to receiving ivosidenib and the patient provided contraceptive counseling on potential risks vs. benefits of taking ivosidenib if patient were to become pregnant.
- ☐ Advise not to breastfeed during treatment with ivosidenib and for at least 1 month after the last dose.

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Additional Inclusion Criteria

One of the following are needed to meet criteria:

☐ Diagnosis of relapsed/refractory acute myeloid leukemia

Defined as relapsed disease after 2 previous inductions OR

Relapsed disease after 1 induction and not suitable for intensive chemotherapy

☐ Newly diagnosed with acute myeloid leukemia AND age ≥ 75 years OR

Not a candidate for intensive induction therapy

☐ Diagnosis of locally advanced or metastatic cholangiocarcinoma

After 1 prior gemcitabine-based or fluorouracil-based regimen