

# Tibsovo (ivosidenib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tibsovo (ivosidenib)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Tibsovo (ivosidenib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of acute myeloid leukemia (AML) (NCCN 2A); **AND**
- II. Individual has test results showing a susceptible isocitrate dehydrogenase-1 (IDH1) mutation; **AND**
- III. Individual cannot use more intensive induction chemotherapy; **OR**
- IV. Individual is using as consolidation therapy as continuation of low-intensity regimen used for induction therapy;

### **OR**

- V. Individual has a diagnosis of relapsed or refractory acute myeloid leukemia (AML) (Label); **AND**
- VI. Individual has test results showing a susceptible isocitrate dehydrogenase-1 (IDH1) mutation;

### **OR**

- VII. Individual has a diagnosis of locally advanced, unresectable or metastatic cholangiocarcinoma (Label, NCCN 2A); **AND**
- VIII. Individual has test results showing a susceptible isocitrate dehydrogenase-1 (IDH1) mutation; **AND**
- IX. Individual has confirmed disease progression on or after one or more prior lines of systemic treatment;

### **OR**

- X. Individual has a diagnosis of conventional or dedifferentiated chondrosarcoma (NCCN 2A); **AND**
- XI. Individual has test results showing a susceptible isocitrate dehydrogenase-1 (IDH1) mutation;

### **OR**

- XII. Individual has a diagnosis of recurrent or progressive predominantly non-enhancing IDH1 mutant astrocytoma (NCCN 2A); **AND**

- XIII. Individual is using as a single agent; **AND**
- XIV. Individual has a Karnofsky performance Status (KPS) of 60 or higher;

**OR**

- XV. Individual has a diagnosis of recurrent or progressive predominantly non-enhancing IDH1 mutant, 1p19q codeleted oligodendroglioma (NCCN 2A); **AND**
- XVI. Individual is using as a single agent; **AND**
- XVII. Individual has a Karnofsky performance Status (KPS) of 60 or higher;

**OR**

- XVIII. Individual has a diagnosis of relapsed or refractory myelodysplastic syndromes (MDS); **AND**
- XIX. Individual has test results showing a susceptible isocitrate dehydrogenase-1 (IDH1) mutation.

**Note:**

Tibsovo has a black box warning for differentiation syndrome which can be fatal if not treated. If differentiation syndrome is suspected, corticosteroid therapy and hemodynamic monitoring should be initiated and continued until symptom resolution.

**Key References:**

1. Abou-Alfa GK, Macarulla T, Javle MM, et al. Ivosidenib in IDH1-mutant, chemotherapy-refractory cholangiocarcinoma (ClarIDHy): a multicentre, randomised, double-blind, placebo-controlled, phase 3 study. *Lancet Oncol.* 2020;21(6):796-807.
2. Tap WD, Villalobos VM, Cote GM, et al. Phase I Study of the Mutant IDH1 Inhibitor Ivosidenib: Safety and Clinical Activity in Patients With Advanced Chondrosarcoma. *J Clin Oncol.* 2020;38(15):1693-1701. doi:10.1200/JCO.19.02492
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2023. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
4. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 21, 2023.
5. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
6. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
7. NCCN Clinical Practice Guidelines in Oncology™. © 2021 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on November 28, 2023.
  - a. Bone Cancer. V3.2023. Revised November 28, 2022.
  - b. Central Nervous System Cancers. V1.2023. Revised March 24, 2023.
  - c. Biliary Tract Cancers. V2.2023. Revised March 10, 2023.
  - d. Acute Myeloid Leukemia. V3.2023. Revised April 5, 2023.
  - e. Myelodysplastic Syndromes. V3.2023. Revised November 10, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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