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 1, 2A); **AND**
II. Individual has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation; **AND**
III. Individual meets one of the following:
    A. Individual is using as induction therapy and cannot use more intensive induction chemotherapy; **OR**
    B. Individual is using as follow-up after induction therapy following response to previous lower intensity therapy; **OR**
    C. Individual is using as consolidation therapy as continuation of low-intensity regimen used for induction therapy; **OR**
    D. Individual has a diagnosis of relapsed or refractory disease;

OR

IV. Individual has a diagnosis of gross residual (R2) disease, locally advanced, unresectable or metastatic cholangiocarcinoma (Label, NCCN 1, 2A); **AND**
V. Individual has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation; **AND**
VI. Individual has disease progression on or after one or more prior lines of systemic treatment;

OR

VII. Individual has a diagnosis of conventional or dedifferentiated chondrosarcoma (NCCN 2A); **AND**
VIII. Individual has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation;

OR

IX. Individual has a diagnosis of recurrent or progressive predominantly non-enhancing IDH1 mutant astrocytoma (NCCN 2A); **AND**
X. Individual is using as a single agent; **AND**
XI. Individual has a Karnofsky performance Status (KPS) of 60 or higher;

OR

XII. Individual has a diagnosis of recurrent or progressive predominantly non-enhancing IDH1 mutant, 1p19q codeleted oligodendroglioma (NCCN 2A); **AND**
XIII. Individual is using as a single agent; **AND**
XIV. Individual is unable to tolerate vorasidenib;

OR

XV. Individual has a diagnosis of IDH1-mutant astrocytoma (NCCN 2A); **AND**
XVI. Individual is using as a single agent; **AND**
XVII. Individual is unable to tolerate vorasidenib;

OR

XVIII. Individual has a diagnosis of myelodysplastic syndromes (MDS) that is relapsed, intolerant or refractory to prior therapies (Label, NCCN 2A); **AND**
XIX. Individual has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation.

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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Updated periodically.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 9, 2025.
    a. Acute Myeloid Leukemia. V2.2025. Revised May 15, 2025.
    b. Biliary Tract Cancers. V1.2025. Revised March 20, 2025.
    c. Bone Cancer. V2.2025. Revised February 28, 2025.
    d. Central Nervous System Cancers. V1.2025. Revised June 3, 2025.
    e. Myelodysplastic Syndromes. V2.2025. Revised January 17, 2025.