

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tibsovo Prior Authorization Policy

- Tibsovo® (ivosidenib tablets –Servier/Les)

REVIEW DATE: 02/23/2022; selected revision 06/22/2022

OVERVIEW

Tibsovo, an isocitrate dehydrogenase-1 (IDH1) inhibitor, is indicated for the treatment of adults with a susceptible *IDH1* mutation as detected by an FDA-approved test for the following uses:¹

- **Acute myeloid leukemia, newly diagnosed disease, in combination with azacitidine or monotherapy**, for patients who are ≥ 75 years of age or who have comorbidities that preclude use of intensive induction chemotherapy.
- **Acute myeloid leukemia, relapsed or refractory disease.**
- **Cholangiocarcinoma, locally advanced or metastatic**, in patients who have been previously treated.

Guidelines

Tibsovo is discussed in the guidelines from the National Comprehensive Cancer Network (NCCN):²

- **Acute Myeloid Leukemia:** NCCN guidelines (version 1.2022 – December 2, 2021) recommend Tibsovo as a preferred therapy for treatment induction for patients with the *IDH1* mutation, as well as in the setting of relapsed or refractory disease (category 2A).³
- **Cholangiocarcinoma:** NCCN guidelines for hepatobiliary cancers (version 5.2021 – September 21, 2021) cite Tibsovo as useful in certain circumstances for patients with cholangiocarcinoma with *IDH1* mutations as subsequent-line therapy if there is disease progression (category 2A).⁴
- **Bone Cancer:** The NCCN guidelines (version 2.2022 – October 8, 2021) recommend Tibsovo for conventional (grades 1 to 3) and dedifferentiated chondrosarcoma in patients with susceptible *IDH1* mutations as useful in certain circumstances (category 2A).⁵

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tibsovo. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tibsovo is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation positive disease as detected by an approved test.
2. **Cholangiocarcinoma.** Approve for 1 year if the patient meets the following (A, B and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation positive disease; AND

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C) Patient has been previously treated with at least one chemotherapy regimen.

Note: Examples are gemcitabine + cisplatin; 5-fluorouracil + oxaliplatin or cisplatin; capecitabine + oxaliplatin or cisplatin; gemcitabine + Abraxane (paclitaxel protein-bound particles intravenous infusion) or capecitabine or oxaliplatin; and FOLFOX (5-fluorouracil, leucovorin, and oxaliplatin).

Other Uses with Supportive Evidence

3. Bone Cancer. Approve for 1 year if the disease is the patient meets the following criteria (A and B):

A) Patient has chondrosarcoma; AND

B) Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation positive disease.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tibsovo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tibsovo® tablets [prescribing information]. Boston, MA: Servier; August 2021.
2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 17, 2022. Search term: ivosidenib
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – December 2, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 17, 2022.
4. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 5.2021 – September 21, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on February 17, 2022.
5. The NCCN Bone Cancers Clinical Practice Guidelines in Oncology (version 2.2022 – October 8, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 17, 2022.

IDH1 – Isocitrate dehydrogenase-1.