PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tibsovo Prior Authorization Policy
- Tibsovo® (ivosidenib tablets –Servier/Les)

REVIEW DATE: 03/06/2024

OVERVIEW

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

- **Acute myeloid leukemia, newly diagnosed disease, in combination with azacitidine or as monotherapy,** in 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**, in adults.
- **Cholangiocarcinoma, locally advanced or metastatic**, in adults who have been previously treated.
- **Myelodysplastic syndrome, relapsed or refractory disease**, in adults.

Guidelines

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

- **Acute Myeloid Leukemia:** NCCN guidelines (version 1.2024 – February 28, 2024) recommend Tibsovo as a single-agent (category 2A) as "Other Recommended Regimen" or in combination with azacitidine (category 1) as "Preferred" therapy for treatment induction for patients with an *IDH1* mutation who are not candidates for intensive induction therapy; and it is also used for follow-up after induction therapy, and consolidation therapy for patients with an *IDH1* mutation. Tibsovo is also recommended for relapsed or refractory disease with *IDH1* mutation (category 2A).[3]
- **Bone Cancer:** NCCN guidelines (version 1.2024 – August 7, 2023) 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]
- **Central Nervous System Cancers:** NCCN guidelines (version 1.2023 – March 24, 2023) recommend Tibsovo for recurrent or progressive *IDH-1* mutant oligodendroglioma World Health Organization (WHO) grade 2 as "Other Recommend Regimens" and WHO grade 3 as "Useful in Certain Circumstances" (both category 2A) and *IDH-1* mutant astrocytoma WHO grade 2 as "Other Recommended Regimens" (category 2A) and WHO grade 3 or 4 as "Useful in Certain Circumstances" (category 2B).[6]
- **Cholangiocarcinoma:** NCCN guidelines for biliary tract cancer (version 3.2023 – November 8, 2023) cite Tibsovo as "Useful in Certain Circumstances" for patients with cholangiocarcinoma with *IDH1* mutations as subsequent-line therapy if there is disease progression (category 1).[4]
- **Myelodysplastic Syndromes:** NCCN guidelines (version 1.2024 – February 12, 2024) recommend Tibsovo for patients with myelodysplastic syndrome with *IDH* 1 o mutation when patients has not experienced a response to other therapies.[7]

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
   - **C)** Patient has been previously treated with at least one chemotherapy regimen.
     Note: Examples are gemcitabine + cisplatin; Imfinzi (durvalumab intravenous infusion) + 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).

3. **Myelodysplastic Syndrome.** 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
   - **C)** Patient has relapsed or refractory disease.

Other Uses with Supportive Evidence

4. **Bone Cancer.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient has chondrosarcoma; AND
   - **B)** Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation-positive disease.

5. **Central Nervous System Cancer**. 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 recurrent or progressive disease; AND
   - **C)** Patient has meets one of the following (i or ii):
     - **i.** Patient has World Health Organization (WHO) grade 2 or 3 oligodendroglioma; OR
     - **ii.** Patient has WHO grade 2 astrocytoma.

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; October 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 4, 2024. Search term: ivosidenib.

3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2024 – February 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 4, 2024.
4. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 3.2023 – November 8, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 4, 2024.
5. The NCCN Bone Cancers Clinical Practice Guidelines in Oncology (version 1.2024 – August 7, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 4, 2024.
6. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 1.2023 – March 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 4, 2024.
7. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 1.2024 – February 12, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 4, 2024.