VENTURA COUNTY
HEALTH CARE PLAN

# PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 03/08/2023; selected revision 04/19/2023 and 11/01/2023

## 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 1.2023 – March 3, 2023) recommend Tibsovo as a single-agent (category 2A) 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 2.2023 – September 28, 2022) 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 recommend regimens" (category 2A) and WHO grade 3 or 4 as "useful in certain circumstances" (category 2B).[6]
- **Cholangiocarcinoma:** NCCN guidelines for hepatobiliary cancers (version 5.2022 – January 13, 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 2A).[4]
- **Myelodysplastic Syndromes:** NCCN guidelines (version 2.2023 – October 17, 2023) state that emerging data are demonstrating effectiveness of Tibsovo and Idhifa® (enasidenib) for patients with myelodysplastic syndrome with *IDH* 1 or *IDH* 2 mutations.[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. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on April 12, 2023. Search term: ivosidenib.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2023 – March 3, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
4. The NCCN Hepatobiliary Cancers Clinical Practice Guidelines in Oncology (version 5.2022 – January 13, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on March 7, 2023.
5. The NCCN Bone Cancers Clinical Practice Guidelines in Oncology (version 2.2023 – September 28, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
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 April 12, 2023.
7. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 2.2023 – October 17, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 27, 2023.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Bone Cancer:** Condition of approval of chondrosarcoma was reworded to Bone Cancer. Chondrosarcoma was added to the criteria. | 02/23/2022 |
| Update | **05/26/2022:** The overview section was updated due to expanded FDA approval to include "in combination with azacitidine" for patients with newly diagnosed Isocitrate dehydrogenase-1 (*IDH1)*-mutated acute myeloid leukemia AML who are ≥ 75 years of age or have comorbidities that precludes intensive induction chemotherapy. | -- |
| Selected Revision | **Acute Myeloid Leukemia:** The duration of approval was changed from 3 years to 1 year.<br>**Cholangiocarcinoma:** The duration of approval was changed from 3 years to 1 year.<br>**Bone Cancer:** The duration of approval was changed from 3 years to 1 year. | 06/22/2022 |
| Annual Revision | No criteria changes. | 03/08/2023 |
| Selected Revision | **Central Nervous System Cancer**: Indication and criteria were added based on changes in NCCN guidelines. | 04/19/2023 |
| Selected Revision | **Myelodysplastic Syndrome**: Indication and criteria were added to FDA-approved indications section. | 11/01/2023 |