



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

INSTRUCTIONS FOR USE

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CIGNA NATIONAL FORMULARY COVERAGE:

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.

- **Tibsovo® (ivosidenib tablets (Servier/Les))**
is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

• **Tibsovo® (ivosidenib tablets (Servier/Les))**
is(are) considered experimental, investigational or unproven for ANY other use(s).

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 (<i>IDH1</i>)-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. Cholangiocarcinoma: The duration of approval was changed from 3 years to 1 year. 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

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