PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Isocitrate Dehydrogenase 1 Inhibitor) – Tibsovo Prior Authorization Policy
- Tibsovo® (ivosidenib tablets –Servier/Les)

REVIEW DATE: 03/04/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tibsovo, an isocitrate dehydrogenase-1 (*IDH1*) inhibitor, is indicated for the treatment of the following 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 3.2026 – November 24, 2025) recommend single-agent Tibsovo (category 2A) or Tibsovo + azacitidine (category 1) for patients with an *IDH1* mutation for treatment induction, follow-up after induction therapy, and consolidation therapy. Single-agent Tibsovo is recommended for patients with an *IDH1* mutation who have relapsed or refractory disease (category 2A).[3]
- **Bone Cancer:** NCCN guidelines (version 2.2026 – December 19, 2025) recommend Tibsovo for conventional (Grades 1 to 3) chondrosarcoma and dedifferentiated chondrosarcoma in patients with susceptible *IDH1* mutations as "Useful in Certain Circumstances" (category 2A).[5]
- **Central Nervous System Cancers:** NCCN guidelines (version 3.2025 – December 5, 2025) recommend Tibsovo for *IDH1* mutant oligodendroglioma (category 2A), *IDH1* mutant astrocytoma (category 2A/2B), and IDH mutant high-grade glioma.[6] These recommendations are specifically for patients who are unable to tolerate Voranigo® (vorasidenib tablets).
- **Cholangiocarcinoma:** NCCN guidelines for biliary tract cancer (version 2.2025 – July 2, 2025) 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 3.2026 – January 12, 2026) recommend Tibsovo for patients with myelodysplastic syndrome with *IDH1* mutation when the patient has not experienced a response to other therapies (category 2A/2B).[7] Tibsovo can also be as initial treatment in patients with higher-risk disease (category 2B).

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 BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation-positive disease.

2. **Cholangiocarcinoma.** Approve for 1 year if the patient meets ALL of 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 of a chemotherapy regimen include one or more of the following agents: cisplatin, Imfinzi (durvalumab intravenous infusion), gemcitabine, Keytruda (pembrolizumab intravenous infusion), 5-fluorouracil, oxaliplatin, capecitabine.

3. **Myelodysplastic Syndrome.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation-positive disease

Other Uses with Supportive Evidence

4. **Bone Cancer.** Approve for 1 year if the patient meets BOTH of 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 ALL of the following (A, B, C, and D):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has isocitrate dehydrogenase-1 (*IDH1*) mutation-positive disease; AND
   C) Patient meets ONE of the following (i, ii, or iii):
      i. Patient has oligodendroglioma; OR
      ii. Patient has astrocytoma; OR
      iii. Patient has high-grade glioma; AND
   D) According to the prescriber, the patient is not a candidate for Voranigo (vorasidenib tablets).

CONDITIONS NOT COVERED

Tibsovo® (ivosidenib tablets - Servier/Les) is(are) considered not medically necessary for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. Tibsovo® tablets [prescribing information]. Boston, MA: Servier/Les; October 2023.
2. The NCCN Drugs & Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2026. Search term: ivosidenib.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 3.2026 – November 24, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2026.
4. The NCCN Biliary Tract Cancers Clinical Practice Guidelines in Oncology (version 2.2025 – July 2, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2026.
5. The NCCN Bone Cancers Clinical Practice Guidelines in Oncology (version 2.2026 – December 19, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2026.

6. The NCCN Central Nervous System Cancers Clinical Practice Guidelines in Oncology (version 3.2025 – December 5, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2026.
7. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 3.2026 – January 12, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 23, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	03/06/2024
Annual Revision	**Cholangiocarcinoma:** The note regarding examples of a chemotherapy regimen was revised. Previously, the note stated, "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)." The revised note now states, "Examples of a chemotherapy regimen include one or more of the following agents: cisplatin, Imfinzi (durvalumab intravenous infusion), gemcitabine, Keytruda (pembrolizumab intravenous infusion), 5-fluorouracil, oxaliplatin, capecitabine" **Central Nervous System Cancer:** The requirement that the patient has recurrent or progressive disease has been removed. The requirement of "World Health Organization (WHO) grade 2 or 3" was removed for a patient with oligodendroglioma. The requirement of "WHO grade 2" was removed for a patient with astrocytoma.	03/12/2025
Update	04/08/2025: The policy name was changed from "Oncology – Tibsovo PA Policy" to "Oncology (Oral - Isocitrate Dehydrogenase 1 Inhibitor) – Tibsovo PA Policy"	N/A
Annual Revision	**Acute Myeloid Leukemia:** The wording "as detected by an approved test" was removed for the requirement which previously stated that the "patient has isocitrate dehydrogenase-1 (*IDH1*) mutation-positive disease as detected by an approved test". **Myelodysplastic Syndrome:** The requirement that the patient has relapsed or refractory disease was removed. **Central Nervous System Cancer:** A requirement that the patient has isocitrate dehydrogenase-1 (*IDH1*) mutation-positive disease was added. The requirement that according to the prescriber, the patient is not a candidate for Voranigo (vorasidenib tablets) was added. An option of approval was added for a patient with high-grade glioma.	03/04/2026