PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/06/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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 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.

- **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 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); 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.

HISTORY

Type of Revision	Summary of Changes	Review Date
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
Annual Revision	No criteria changes.	03/06/2024