UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1257-9
Program	Prior Authorization/Notification
Medication	Tibsovo® (ivosidenib)
P&T Approval Date	9/2018, 6/2019, 6/2020, 6/2021, 10/2021, 10/2022, 10/2023, 1/2024, 1/2025
Effective Date	4/1/2025

1. Background:

Tibsovo® (ivosidenib) is an isocitrate dehydrogenase-1 inhibitor indicated for the treatment of adult patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation with relapsed or refractory acute myeloid leukemia (AML) or in combination with azacitidine or as monotherapy for the treatment of newly diagnosed AML in adults who are ≥ 75 years old, or who have comorbidities that preclude the use of intensive induction chemotherapy. Tibsovo is indicated for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible IDH1 mutation. Tibsovo is also indicated in adult patients with a susceptible IDH1 mutation with locally advanced or metastatic cholangiocarcinoma who have previously been treated.

The National Cancer Comprehensive Network (NCCN) guideline also recommends the use of Tibsovo in susceptible IDH1 mutation-positive AML patients who are 60 to 74 years old and receiving Tibsovo as treatment induction when not a candidate for intensive remission induction therapy or declines, or as post-induction therapy following response to previous lower intensity therapy with the same regimen. The NCCN guidelines also recommend the use of Tibsovo in IDH1 mutation-positive patients with either conventional (grades 1-3) or dedifferentiated chondrosarcoma, recurrent or progressive IDH mutant 1p19q codeleted oligodendroglioma WHO Grade 2 or 3, and recurrent or progressive IDH-mutant astrocytoma WHO Grade 2, 3, or 4.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. Patients less than 19 years of age

1. **Tibsovo** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. Acute Myeloid Leukemia (AML)

1. **Initial Authorization**

   a. **Tibsovo** will be approved based on **all** of the following criteria:

      (1) Diagnosis of acute myeloid leukemia (AML)

      -AND-

      (2) AML is IDH1 mutation-positive

      -AND-

      (3) **One** of the following:

         (a) Disease is relapsed or refractory

         -OR-

         (b) **Both** of the following:

            i. New diagnosis of AML

            -AND-

            ii. **One** of the following:
            - Patient ≥ 75 years old
            - Patient has comorbidities that preclude the use of intensive induction chemotherapy
            - Patient is ≥ 60 years old and not a candidate for or declines intensive induction therapy
            - Patient is ≥ 60 years old and receiving post-induction therapy following response to previous lower intensity therapy

   Authorization will be issued for 12 months.

2. **Reauthorization**

   a. **Tibsovo** will be approved based on the following criterion:

      (1) Patient does not show evidence of progressive disease while on Tibsovo therapy

      Authorization will be issued for 12 months.

C. Bone Cancer

1. **Initial Authorization**

   a. **Tibsovo** will be approved based on **all** of the following criteria:

(1) Diagnosis of chondrosarcoma

-AND-

(2) Susceptible IDH1 mutation-positive

-AND-

(3) Disease is **one** of the following:

(a) Conventional (grades 1-3)
(b) Dedifferentiated

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tibsovo** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tibsovo therapy

Authorization will be issued for 12 months.

D. Biliary Tract Cancer

1. **Initial Authorization**

a. **Tibsovo** will be approved based on **all** of the following criteria:

(1) Diagnosis of cholangiocarcinoma

-AND-

(2) Susceptible IDH1 mutation-positive

-AND-

(3) Disease is **one** of the following:

(a) Locally advanced
(b) Unresectable
(c) Metastatic

-AND-

(4) Disease has progressed on or after systemic treatment

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tibsovo** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tibsovo therapy

Authorization will be issued for 12 months.

E. Oligodendroglioma

1. **Initial Authorization**

a. **Tibsovo** will be approved based on **all** of the following criteria:

(1) Diagnosis of oligodendroglioma

-AND-

(2) Disease is recurrent or progressive

-AND-

(3) Presence of **both** of the following:

(a) IDH1 mutation
(b) 1p19q codeletion

-AND-

(4) Disease is WHO grade 2 or 3

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tibsovo** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tibsovo therapy

Authorization will be issued for 12 months.

F. Astrocytoma

1. **Initial Authorization**

a. **Tibsovo** will be approved based on **all** of the following criteria:

(1) Diagnosis of astrocytoma

-AND-

(2) Disease is recurrent or progressive

-AND-

(3) Presence of IDH1 mutation

-AND-

(4) Disease is WHO grade 2, 3, or 4

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tibsovo** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tibsovo therapy

Authorization will be issued for 12 months.

G. Myelodysplastic Syndromes (MDS)

1. **Initial Authorization**

a. **Tibsovo** will be approved based on **all** of the following criteria:

(1) Diagnosis of myelodysplastic syndrome (MDS)

-AND-

(2) Disease is relapsed or refractory

-AND-

(3) Presence of IDH1 mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Tibsovo** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Tibsovo therapy

Authorization will be issued for 12 months.

H. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National

Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tibsovo [package insert]. Boston, MA: Servier Pharmaceuticals LLC; October 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed November 25, 2024.

Program	Prior Authorization/Notification – Tibsovo (ivosidenib)
Change Control	
9/2018	New program.
6/2019	Updated background and criteria to include new indication for newly diagnosed AML in patients ≥ 75 years of age or with comorbidities that preclude intensive induction chemotherapy.
6/2020	Annual review. Added general NCCN recommendations for use criteria. Updated references.
6/2021	Annual review. Added criteria per NCCN guidelines for chondrosarcoma and cholangiocarcinoma. Updated reference.
10/2021	Updated background and criteria for AML biliary tract cancer to align with both label and NCCN guidelines. Updated references.
10/2022	Annual review. Added state mandate footnote. Updated background and criteria to more closely align with the NCCN guidelines. Updated references.
10/2023	Annual review. Added criteria for oligodendroglioma and astrocytoma per NCCN guidelines. Updated references.
1/2024	Updated background and criteria to include new indication for relapsed or refractory MDS with a susceptible IDH1 mutation. Updated references.
1/2025	Annual review. Updated criteria for oligodendroglioma and astrocytoma per NCCN guidelines. Updated references.