UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tibsovo

Program	Prior Authorization
Medication	Tibsovo® (ivosidenib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2018
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Tibsovo® (ivosidenib) is an isocitrate dehydrogenase-1 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH-1) mutation, or in adult patients with newly diagnosed AML who are ≥ 75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation.

2. Coverage Criteria:

A. <u>Acute Myeloid Leukemia (AML)</u>

1. <u>Initial Authorization</u>

a. Tibsovo will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of acute myeloid leukemia (AML)

-AND-

(2) AML is IDH1 mutation-positive

-AND-

(3) **<u>One</u>** of the following:

(a) Disease is relapsed or refractory
(b) Patient is ≥ 75 years old

(c) Patient has comorbidities that preclude the use of intensive induction chemotherapy

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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Tibsovo** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Tibsovo therapy

Authorization will be issued for 12 months.

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]. Cambridge, MA: Agios Pharmaceuticals, Inc.; May 2019.

2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May7, 2020.

Program	Prior Authorization
Change Control	
Date	Change
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. Updated reference. Removed specific test from background section. Removed black box warning from background section. Added Additional Clinical Rules section.