



## Commercial/Healthcare Exchange PA Criteria

Effective: September 27<sup>th</sup>, 2018

**Prior Authorization:** Tibsovo

**Products Affected:** Tibsovo (Ivosidenib) oral tablets

**Medication Description:**

Tibsovo (Ivosidenib) is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

**Covered Uses:** Acute Myeloid Leukemia

**Exclusion Criteria:** N/A

**Required Medical Information:**

- Previous therapies tried
- Presence of isocitrate dehydrogenase-1 (IDH1) mutation confirmed by an FDA approved test

**Age Restrictions:**

Relapsed or Refractory AML: 18 years of age or older

Newly Diagnosed AML: 75 years of age or older

**Prescriber Restrictions:** Prescribed by or in consultation with an oncologist.

**Coverage Duration:**

Initial: 12 months

Continuation: 3 years

**Other Criteria:**

**Relapsed or Refractory AML:** Approve if the patient meets the following criteria (A, B, C, and D):

- A. Patient is at least 18 years old; **AND**
- B. Patient has a diagnosis of acute myeloid leukemia (AML); **AND**
- C. Patient's disease is relapsed or refractory; **AND**
- D. Patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation has been detected by an FDA-approved test.

**Newly Diagnosed AML:** Approve if the patient meets the following criteria (A, B, and C)

- A) Patient is at least 75 years old; **AND**
- B) Patient has been newly diagnosed with acute myeloid leukemia (AML); **AND**
- C) Patient has comorbidities that preclude use of intensive induction chemotherapy

**References:**

1. TIBSOVO® Full Prescribing Information (U.S.). Agios Pharmaceuticals, Inc. Cambridge, MA. 2018

Last Res. July 1st, 2019



Confidential Information

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2. FDA approves first targeted treatment for patients with relapsed or refractory acute myeloid leukemia who have a certain genetic mutation. FDA News Release. 20 July 2018.  
<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614115.htm>
3. DiNardo C. Durable Remissions from Ivosidenib in IDH1-Mutated Relapsed or Refractory AML. New England Journal of Medicine. June 2, 2018

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	09/27/2018
2	Policy Revision	Updated Criteria to match FDA label	All	5/6/2019
3	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019

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