Commercial/Healthcare Exchange PA Criteria

Effective: September 27th, 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

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

Rev #	Type of Change	Summary of Change	Sections Affected	Date
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