IVOSIDENIB

Generic	Brand	HICL	GCN	Exception/Other
IVOSIDENIB	TIBSOVO	45096		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, continue to #2.

2. Does the patient have a new diagnosis of acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
   - The patient meets **ONE** of the following criteria:
     - The patient is 75 years of age or older
     - The patient is 18 years of age or older **AND** has comorbidities that preclude the use of intensive induction chemotherapy

   If yes, **approve for 12 months by HICL with a quantity limit of #2 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **IVOSIDENIB (Tibsovo)** requires a diagnosis of acute myeloid leukemia (AML). In addition, the following criteria must be met:
   For patients with relapsed or refractory acute myeloid leukemia (AML), approval requires the following:
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
   - The patient is 18 years of age or older

   For patients with a new diagnosis of acute myeloid leukemia (AML), approval requires the following:
   - The patient has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved diagnostic test
   - The patient meets **ONE** of the following criteria:
     - The patient is 75 years of age or older
     - The patient is 18 years of age or older **AND** has comorbidities that preclude the use of intensive induction chemotherapy

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tibsovo.

REFERENCES

- Tibsovo [Prescribing Information]. Cambridge, MA: Agios Pharmaceuticals; May 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 06/01/19

Created: 11/18
Client Approval: 05/19

P&T Approval: 10/18