



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

IVOSIDENIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVOSIDENIB	TIBSOVO	45096		GPI-10 (2153494000)	

**GUIDELINES FOR USE**

1. Does the patient have a new diagnosis of acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
  - The requested medication will be used in combination with azacitidine or as monotherapy
  - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

If yes, continue to #2.  
If no, continue to #3.
2. Does the patient meet **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 or GPI-10 with a quantity limit of #2 per day.**  
If no, do not approve.  
**DENIAL TEXT:** See the denial text at the end of the guideline.
3. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
  - The patient is 18 years of age or older
  - The patient's cancer has a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**  
If no, continue to #4.
4. Does the patient have a diagnosis of locally advanced or metastatic cholangiocarcinoma and meet **ALL** of the following criteria?
  - The patient is 18 years of age or older
  - The patient's cancer has an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test
  - The patient's cancer has been previously treated

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**  
If no, do not approve.  
**DENIAL TEXT:** See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

**DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **IVOSIDENIB (Tibsovo)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
  - 1. Acute myeloid leukemia (AML: a type of blood cancer)
  - 2. Locally advanced or metastatic cholangiocarcinoma (bile duct cancer that has spread from where it started to nearby tissue/lymph nodes or to other parts of the body)
- B. **If you have a new diagnosis of acute myeloid leukemia, approval also requires:**
  - 1. The requested medication will be used in combination with azacitidine or as monotherapy (one drug)
  - 2. Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: type of enzyme) mutation as detected by a Food and Drug Administration (FDA)-approved test
  - 3. You meet ONE of the following:
    - a. You are 75 years of age or older
    - b. You are 18 years of age or older AND have comorbidities (additional diseases) that prevent the use of intensive induction chemotherapy (start of a type of cancer treatment)
- C. **If you have relapsed or refractory acute myeloid leukemia, approval also requires:**
  - 1. You are 18 years of age or older
  - 2. Your cancer has a susceptible (can be treated with the drug) isocitrate dehydrogenase-1 (IDH1: type of enzyme) mutation as detected by a Food and Drug Administration (FDA)-approved test
- D. **If you have locally advanced or metastatic cholangiocarcinoma, approval also requires:**
  - 1. You are 18 years of age or older
  - 2. Your cancer has an isocitrate dehydrogenase-1 (IDH1: type of enzyme) mutation as detected by a Food and Drug Administration (FDA)-approved test
  - 3. Your cancer has been previously treated

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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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 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/18/22

Created: 11/18

Client Approval: 06/22

P&T Approval: 07/22