Reference number(s)
2635-A

Specialty Guideline Management
Tibsovo

Products Referenced by this Document

Brand Name	Generic Name
Tibsovo	ivosidenib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

Newly Diagnosed Acute Myeloid Leukemia

Tibsovo is indicated in combination with azacitidine or as monotherapy for the treatment of newly-diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.

Relapsed or Refractory Acute Myeloid Leukemia

Tibsovo 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.

Relapsed or Refractory Myelodysplastic Syndromes

Tibsovo is indicated for the treatment of adult patients with relapsed or refractory myelodysplastic syndromes (MDS) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Locally Advanced or Metastatic Cholangiocarcinoma

Tibsovo is indicated for the treatment of adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.

Compendial Uses[2]

- AML with an IDH1 mutation
- Cholangiocarcinoma with an IDH1 mutation
- Conventional (grades 1-3) or dedifferentiated chondrosarcoma with a susceptible IDH-1 mutation
- Myelodysplastic Syndromes (MDS)
- Central Nervous System (CNS) Cancers:
    - IDH mutant Astrocytoma
    - IDH mutant Oligodendroglioma

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: medical record documentation of isocitrate dehydrogenase-1 (IDH1) mutation

Coverage Criteria

Acute Myeloid Leukemia (AML)[1,2]

Authorization of 12 months may be granted for treatment of newly diagnosed AML with a susceptible IDH1 mutation when any of the following criteria is met:

- Member is 75 years of age or older and the requested medication will be used as a single agent or in combination with azacitidine
- Member is not a candidate for or declines intensive induction therapy and the requested medication will be used as a single agent or in combination with azacitidine

Authorization of 12 months may be granted for post-induction therapy for AML with a susceptible IDH1 mutation when all of the following criteria are met:

- The requested medication will be used as a single agent or in combination with azacitidine
- Member has experienced response to Tibsovo therapy

Authorization of 12 months may be granted for treatment of relapsed or refractory AML with a susceptible IDH1 mutation, as a single agent.

Myelodysplastic Syndromes (MDS)[1,2]

Authorization of 12 months may be granted for subsequent treatment of MDS in members with a susceptible IDH1 mutation.

Cholangiocarcinoma[1,2]

Authorization of 12 months may be granted for subsequent treatment of unresectable, resected gross residual (R2), locally advanced or metastatic cholangiocarcinoma as a single agent in members with an IDH1 mutation.

Chondrosarcoma[2]

Authorization of 12 months may be granted for treatment of conventional (grades 1-3) or dedifferentiated chondrosarcoma in members with a susceptible IDH1 mutation.

CNS Cancers[2]

Authorization of 12 months may be granted for treatment as a single agent of the following types of IDH1 mutant CNS cancer:

- Astrocytoma (WHO grade 2) and either of the following criteria is met:
  - Member has recurrent or progressive disease, or
  - The requested medication will be used as adjuvant treatment
- Oligodendroglioma (WHO grade 2 or 3) and member has recurrent or progressive disease
- Oligodendroglioma (WHO grade 2) and the requested medication will be used as adjuvant treatment

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

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References

1. Tibsovo [package insert]. Boston, MA: Servier Pharmaceuticals LLC; October 2023.
2. The NCCN Drugs & Biologics Compendium® © 2025 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 7, 2025.