



Tibsovo (ivosidenib)
Effective 08/01/19

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

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

Treatment of relapsed or refractory acute myeloid leukemia (AML) in adult patients with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an approved test.

All other indications are considered experimental/investigational and are not a covered benefit.

Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and clinical documentation has been submitted:

1. Documented diagnosis of acute myeloid leukemia with a susceptible IDH1 mutation as detected by an FDA-approved test **AND**
2. Documented relapsed or refractory disease **AND**
3. The prescribing physician is an oncologist or hematologist **AND**
4. Requested quantity does not exceed 60 tablets per 30 days

AllWays Health Partners may authorize coverage for use for other cancer diagnoses outside of FDA indications provided effective treatment with such drug is recognized as a “Medically Accepted Indication” according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus. Clinical



documentation supporting the drug's effectiveness in treating the intended cancer, including the applicable NCCN guideline(s) is required.

Limitations

1. Approvals will be granted for 12 months.
2. The following quantity limits apply:

Tibsovo	60 tablets per 30 days
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References

1. Tibsovo (ivosidenib) [prescribing information]. Cambridge, MA: Agios Pharmaceuticals, Inc; July 2018.
2. DiNardo CD, Stein EM, de Botton S, et al. Durable remissions with ivosidenib in IDH1-mutated relapsed or refractory AML. N Engl J Med. 2018;378(25):2386-2398. 10.1056/NEJMoa1716984
3. Döhner H, Estey E, Grimwade D, et al. Diagnosis and management of AML in adults: 2017 ELN recommendations from an international expert panel. Blood 2017; 129:424Sprycel (dasatinib) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2017

Review History

04/17/19 – Reviewed
08/01/19 – Implemented

Disclaimer

AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin, age, disability, or sex.