Mass General Brigham
Health Plan

Tibsovo (ivosidenib)
Effective 01/01/2023

Plan	☒ MassHealth UPPL ☒Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
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

Ivosidenib is an oral small-molecule inhibitor of the mutant isocitrate dehydrogenase 1 (IDH1) enzyme. Susceptible IDH1 mutations can lead to increased levels of 2-hydroxyglutarate (2-HG) in leukemia cells. 2-HG inhibits alpha-ketoglutarate-dependent enzymes, resulting in impaired hematopoietic differentiation In IDH1 mutated AML blood samples, ivosidenib decreased intracellular levels of 2-HG, reduced blast counts, and induced differentiation (resulting in increased percentages of mature myeloid cells). IDH1 mutations occur in ~6% to10% of patients with acute myeloid leukemia.

Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with Tibsovo, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

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

Acute Myeloid Leukemia (AML), newly diagnosed

1. The member is ≥ 60 years of age
2. The diagnosis has been confirmed with a susceptible IDH1 mutation as detected by an FDA-approved test.
3. The prescribing physician is an oncologist or hematologist

Acute Myeloid Leukemia (AML), relapsed or refractory

1. The member is at least 18 years of age
2. The member has been diagnosed with relapsed or refractory AML

3. The diagnosis has been confirmed with a susceptible IDH1 mutation as detected by an FDA-approved test.
4. The prescribing physician is an oncologist or hematologist

Cholangiocarcinoma, locally advance or metastatic

1. The member is at least 18 years of age
2. The diagnosis has been confirmed with a susceptible IDH1 mutation as detected by an FDA-approved test.
3. The prescribing physician is an oncologist or hematologist
4. The member has had prior treatment for diagnosis with at least one systemic therapy

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.

Continuation of Therapy

Reauthorization may be granted when documentation has been submitted that there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Limitations

1. Initial approvals and Reauthorizations will be granted for 12 months.
2. The following quantity limits apply:

Tibsovo	60 tablets per 30 days

References

1. Tibsovo (ivosidenib) [prescribing information]. Boston, MA: Servier Pharmaceuticals; May 2022
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
4. Zhu AX, Macarulla T, Javle MM, et al. Final Overall Survival Efficacy Results of Ivosidenib for Patients With Advanced Cholangiocarcinoma With IDH1 Mutation: The Phase 3 Randomized Clinical ClarIDHy Trial. JAMA Oncol 2021; 7:1669

Review History

04/17/2019 – Reviewed
08/01/2019 – Implemented
05/20/2020 – reviewed and Updated May P&T Mtg; updated references; added new indication of relapsed or refractory AML; updated age requirement to match MH. Effective 8/1/20.
09/21/2022- reviewed and updated at Sept. P&T: added new indication and criteria for cholangiocarcinoma, separated newly diagnosed and refractory/relapsed AML diagnosis to align with FDA age limits; references updated; QL moved from Coverage Guidelines to Limitations; separated out Comm/Exch vs. MH criteria.