**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% to 10% of patients with acute myeloid leukemia.

**Coverage Guidelines**

Authorization may be granted for members 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 criteria are met, and documentation has been submitted:

1. Member is ≥ 60 years of age and is diagnosed with one of the following:
   a. Relapsed or refractory acute myeloid leukemia
   b. Newly-diagnosed acute myeloid leukemia, with comorbidities that preclude the use of intensive induction chemotherapy
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. 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:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Limitation</th>
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<tr>
<td>Tibsovo</td>
<td>60 tablets per 30 days</td>
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References

Sprycel (dasatinib) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; November 2017

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.

Disclaimer
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