Drug Therapy Guidelines

<table>
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<tr>
<th>Medical Benefit</th>
<th>Applicable*</th>
<th>Effective: 3/7/22</th>
</tr>
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<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>x</td>
<td>Next Review: 12/22</td>
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<td>Pharmacy- Formulary 2</td>
<td>x</td>
<td>Date of Origin: 3/22</td>
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<tr>
<td>Pharmacy- Formulary 3/Exclusive</td>
<td>x</td>
<td>Review Dates: 12/21</td>
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<td>Pharmacy- Formulary 4/AON</td>
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I. Medication Description

Scemblix is an ABL/BCR-ABL1 tyrosine kinase inhibitor. Asciminib inhibits the ABL1 kinase activity of the BCR-ABL1 fusion protein by binding to the ABL myristoyl pocket. In studies conducted in in vitro or animal models of CML, asciminib showed activity against wild-type BCR-ABL1 and several mutant forms of the kinase, including the T315I mutation.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage of Scemblix is available when the following criteria have been met:

- Member is at least 18 years of age AND
- The medication is prescribed by a hematologist/oncologist AND
- The requested use is supported by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines (NCCN Guidelines®) and/or NCCN Drugs & Biologics Compendium (NCCN Compendium®) with a recommendation of category level 1 or 2A.

IV. Quantity Limitations

Coverage is available to allow for sufficient quantities to allow for dosing in accordance with the FDA-approved prescribing information.

V. Coverage Duration

Coverage is available for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Stabilization of disease or in absence of disease progression AND
- Absence of unacceptable toxicity from the drug
VII. Billing/Coding Information

Scemblix is available as 20mg and 40mg tablets.

VIII. Summary of Policy Changes

- 3/7/22: new policy

IX. References

4. Scemblix (asciminib) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; October 2021

*These guidelines are not applicable to benefits covered under Medicare Advantage. Medicare Advantage benefit coverage requests are reviewed in accordance with the guidance set forth in Chapter 15 Section 50 of the Centers for Medicare & Medicaid Services Medicare Benefit Policy Manual.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.