Idhifa

Description

Idhifa (enasidenib)

Background
Idhifa is an oral cancer agent that inhibits isocitrate dehydrogenase-2 (IDH2). Idhifa is indicated for the treatment of acute myeloid leukemia (AML) which is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow (1).

Regulatory Status
FDA-approved indication: Idhifa is an isocitrate dehydrogenase-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test (1).

Idhifa has a boxed warning for differentiation syndrome which may be life-threatening if not treated. Differentiation syndrome is associated with rapid proliferation and differentiation of myeloid cells. While there is no diagnostic test for differentiation syndrome, symptoms in patients treated with Idhifa included acute respiratory distress represented by dyspnea and/or hypoxia, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction (1).

Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

Related policies
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Idhifa may be considered medically necessary in patients 18 years or older with relapsed or refractory acute myeloid leukemia (AML) and if the conditions indicated below are met.

Idhifa is considered investigational in patients below 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**

18 years of age and older

**Diagnosis**

The patient must have the following:

1. Relapsed or refractory acute myeloid leukemia (AML)
   a. Isocitrate dehydrogenase-2 (IDH2) mutation AML detected by FDA-approved test
   b. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome

**Prior – Approval Renewal Requirements**

**Age**

18 years of age and older

**Diagnosis**

The patient must have the following:

1. Relapsed or refractory acute myeloid leukemia (AML)
   a. NO disease progression or unacceptable toxicity
   b. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome
Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

<table>
<thead>
<tr>
<th>Strength</th>
<th>Quantity per 90 days</th>
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<tbody>
<tr>
<td>50 mg</td>
<td>90 tablets per 90 days OR</td>
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Duration 12 months

Prior – Approval Renewal Limits

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Duration 12 months

Rationale

Summary

Idhifa is indicated for the treatment of acute myeloid leukemia (AML) which is a rapidly progressing cancer that forms in the bone marrow and results in an increased number of abnormal white blood cells in the bloodstream and bone marrow. Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Idhifa while maintaining optimal therapeutic outcomes.

References

Section: Prescription Drugs  Effective Date: April 1, 2019
Subsection: Antineoplastic Agents  Original Policy Date: August 18, 2017
Subject: Idhifa  Page: 4 of 4

Policy History

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<th>Date</th>
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<tr>
<td>August 2017</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2017</td>
<td>Annual review</td>
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<tr>
<td>December 2017</td>
<td>Annual review</td>
</tr>
<tr>
<td>June 2018</td>
<td>Annual editorial review</td>
</tr>
<tr>
<td>November 2018</td>
<td>Addition of quantity limits to initiation and renewal criteria</td>
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<tr>
<td>March 2019</td>
<td>Annual review</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 15, 2019 and is effective on April 1, 2019.