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5.21.098

Section:	Prescription Drugs	**Effective Date:**	January 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 18, 2017
Subject:	Idhifa	**Page:**	1 of 4

Last Review Date: December 8, 2023

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
Rezlidhia, Tibsovo

Policy

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** if the conditions indicated below are met.

Idhifa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

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

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

Strength	Quantity
50 mg	90 tablets per 90 days **OR**
100 mg	90 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

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

1. Idhifa [package insert]. Princeton, NJ: Bristol-Myers Squibb company; August 2022.
2. NCCN Drugs & Biologics Compendium® Enasidenib 2023. National Comprehensive Cancer Network, Inc. Accessed on October 2, 2023.

Policy History

Date	Action
August 2017	Addition to PA
September 2017	Annual review
December 2017	Annual review

June 2018	Annual editorial review Addition of quantity limits to initiation and renewal criteria
November 2018	Annual review
March 2019	Annual review
June 2020	Annual review and reference update
June 2021	Annual review and reference update
June 2022	Annual review and reference update
March 2023	Annual review and reference update. Changed policy number to 5.21.098
December 2023	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 8, 2023 and is effective on January 1, 2024.