

Clinical Policy Title:	enasidenib
Policy Number:	RxA.176
Drug(s) Applied:	Idhifa®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acute Myeloid Leukemia (AML) (must meet all):

1. Diagnosis of AML;
2. The requested medication and member diagnosis meet one of the following (a or b):
 - a. Used as single agent in patients 60 years or older and one of the following (i or ii):
 - i. For treatment induction when member is not a candidate for intensive remission induction therapy;
 - ii. For post-induction therapy following response to previous lower intensity therapy with same regimen;
 - b. Members with relapsed/refractory disease and the requested medication meets one of the following (i or ii):
 - i. Prescribed as monotherapy;
 - ii. Prescribed as a component of repeating the initial successful induction regimen if late relapse (\geq 12 months since induction regimen) if not administered continuously and not stopped due to development of clinical resistance;
3. Presence of an IDH2 mutation.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Acute Myeloid Leukemia (AML) (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
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This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Policy established.	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated to all lines of business. 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Commercial approval duration was updated from "Length of benefit to 6 months for initial approval criteria & 12 months for continued therapy approval. 5. References were reviewed and updated. 	07/08/2020	09/14/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. References were updated. 2. Initial approval criteria has been updated per NCCN AML guideline recommendation under section I.A.4. 	02/24/2021	06/10/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.4.a.i updated from Member is not a candidate for intensive remission induction therapy; to For treatment induction when member is not a candidate for intensive remission induction therapy; 2. Initial Approval Criteria I.A.4.B.ii - updated from Prescribed as a component of repeating the initial successful induction regimen; to Prescribed as a component of repeating the initial successful induction regimen if late relapse (\geq; 12 months since induction regimen) if not administered continuously and not stopped due to development of clinical resistance; 3. References were reviewed and updated. 	01/13/2022	04/18/2022
Policy was reviewed: <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A: Commercial approval duration updated from 6 months to 12 months. 2. References were reviewed and updated. 	01/18/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: <ol style="list-style-type: none"> 1. Removed prescriber restrictions. 2. Removed age restrictions. 3. Removed dose restrictions. 	8/28/2024	9/13/2024

<ul style="list-style-type: none"> 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated. 		
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025