ENASIDENIB

Generic	Brand	HICL	GCN	Exception/Other
ENASIDENIB	IDHIFA	44450		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) **AND** meet **ALL** of the following criteria?
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL with a quantity limit of #1 tablet per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **ENASIDENIB (Idhifa)** requires a diagnosis of relapsed or refractory acute myeloid leukemia (AML). In addition, the following criteria must be met:
   - The patient is isocitrate dehydrogenase-2 (IDH2) mutation positive as detected by an FDA-approved diagnostic test
   - The patient is 18 years of age or older

RATIONALE
Promote appropriate utilization of **ENASIDENIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
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.

DOSAGE AND ADMINISTRATION
The recommended dose of Idhifa is 100mg taken orally once daily with or without food. Idhifa tablets should not be split or crushed.

REFERENCES
- Idhifa [Prescribing Information]. Summit, NJ: Celgene Corporation; August 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/18
Created: 08/17
Client Approval: 12/17
P&T Approval: 10/17