MIDOSTAURIN

Generic	Brand	HICL	GCN	Exception/Other
MIDOSTAURIN	RYDAPT	44227		

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
   - The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
   - The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL with a quantity limit of #56 capsules per 28 days.**
   If no, continue to #2.

2. Does the patient have a diagnosis of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)?

   If yes, **approve for 12 months by HICL with a quantity limit of #224 capsules per 28 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **MIDOSTAURIN (Rydapt)** requires a diagnosis of newly diagnosed acute myeloid leukemia (AML), aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL). The following criteria must also be met:
   For newly diagnosed acute myeloid leukemia (AML), approval requires all of the following:
   - The patient is FLT3 mutation-positive as detected by an FDA-approved diagnostic test
   - The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
   - The requested medication will not be used as a single-agent induction therapy for the treatment of patients with AML
   - The patient is 18 years of age or older

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

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MIDOSTAURIN

FDA APPROVED INDICATIONS

Rydapt is a kinase inhibitor indicated for the treatment of adults with:

- Newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation
- Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

Limitations of Use:
Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

DOSAGE AND ADMINISTRATION

Rydapt is available as 25 mg capsules. Rydapt should be taken twice daily with food. Rydapt capsules should not be opened or crushed.

Recommended Dosage in Acute Myeloid Leukemia

The recommended dose of Rydapt for patients with acute myeloid leukemia is 50 mg orally twice daily with food on Days 8 to 21 of each cycle of induction with cytarabine and daunorubicin and on Days 8 to 21 of each cycle of consolidation with high-dose cytarabine.

FLT3 mutation status must be reported using the FDA-approved, in-vitro companion diagnostic LeukoStrat® CDx FLT3 Mutation Assay to ensure correct selection of patients eligible to be treated with Rydapt.

Recommended Dosage in ASM, SM-AHN, and MCL

The recommended dose of Rydapt for patients with ASM, SM-AHN, and MCL is 100 mg orally twice daily with food. Continue treatment until disease progression or unacceptable toxicity occurs. Dose modifications for therapy-related toxicities can be found in the prescribing information.

REFERENCES

- Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; April 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/18
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P&T Approval: 07/17