STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MIDOSTAURIN

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MIDOSTAURIN	RYDAPT	44227		GPI-10 (2153303000)	

GUIDELINES FOR USE

1. Does the patient have newly diagnosed acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - 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

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #56 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) **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #224 per 28 days.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MIDOSTAURIN (Rydapt)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Newly diagnosed acute myeloid leukemia (AML: a type of blood cancer)
      2. Aggressive systemic mastocytosis (ASM: a type of blood disorder)
      3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN: type of blood cancer)
      4. Mast cell leukemia (MCL: type of blood cell cancer)

   (Denial text continued on next page)

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MIDOSTAURIN

GUIDELINES FOR USE (CONTINUED)

B. **If you have newly diagnosed acute myeloid leukemia, approval also requires:**
   1. You are 18 years of age or older
   2. You are FLT3 (type of gene) mutation-positive as detected by a Food and Drug Administration (FDA)-approved diagnostic test
   3. The requested medication will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (cancer drugs)
   4. The requested medication will not be used by itself to start treatment (single-agent induction therapy)

C. **If you have aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia, approval also requires:**
   1. You are 18 years of age or older

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the prescribing information and/or drug monograph for Rydapt.

REFERENCES

- Rydapt [Prescribing Information]. East Hanover, New Jersey: Novartis Pharmaceuticals; November 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/22
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