Reference number(s)
1817-A

Specialty Guideline Management
Rydapt

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Rydapt	midostaurin

Indications

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

- Rydapt is indicated, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by an FDA approved test.

Limitations of Use:

- Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.
- Rydapt is indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

Compendial Uses[2-4]

- Acute Myeloid Leukemia (AML): Relapsed/refractory disease, post-induction therapy, re-induction of residual disease, and maintenance therapy
- Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions
- Systemic mastocytosis

All other indications are considered experimental/investigational and are not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: Medical record documentation of FLT3 mutation or FGFR1 rearrangement (where applicable)

Coverage Criteria

Acute Myeloid Leukemia (AML)[1,2]

Authorization of 12 months may be granted for the treatment of FLT3 mutation-positive AML when it is not used as a single-agent for induction therapy.

Systemic Mastocytosis[1,2]

Authorization of 12 months may be granted for the treatment of aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) as a single agent.

Authorization of 12 months may be granted for the treatment of symptomatic indolent systemic mastocytosis (ISM) or smoldering systemic mastocytosis (SSSM) as a single agent after first-line therapy with a clinical trial or avapritinib.

Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions[2]

Authorization of 12 months may be granted for the treatment of myeloid and/or lymphoid neoplasms with eosinophilia with FGFR1 or FLT3 rearrangement in the chronic phase or blast phase.

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Continuation of Therapy

Acute Myeloid Leukemia (AML)[1,2]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity.

Systemic Mastocytosis, Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions[1,2]

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Rydapt [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2023.
2. The NCCN Drugs & Biologics Compendium®. © 2025 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed May 5, 2025.