BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.21.093

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	May 12, 2017
Subject:	Rydapt	**Page:**	1 of 4

Last Review Date: March 6, 2026

Rydapt

Description

Rydapt (midostaurin)

Background
Rydapt is an oral cancer agent that inhibits multiple receptor tyrosine kinases. Rydapt is indicated for the treatment of acute myeloid leukemia (AML), an aggressive cancer of the blood and bone, and advanced systemic mastocytosis. Some patients with AML have a gene mutation in the FLT3 cell-surface receptor which can result in faster disease progression, higher relapse rate, and lower survival rates than other forms of AML. Rydapt works by blocking the FLT3 receptor signaling and cell proliferation and inducing apoptosis of certain leukemic cells (1).

Regulatory Status
FDA-approved indications: Rydapt is a kinase inhibitor indicated for the treatment of adult patients with:

1. 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 (1).
2. Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) (1).

Limitations of Use: (1)

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

Rydapt may cause fetal harm when administered to a pregnant women. Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating therapy. Advise females and males with female partners to use effective contraception during treatment with Rydapt and for 4 months after the last dose (1).

Cases of interstitial lung disease and pneumonitis, some fatal, have occurred in patients taking Rydapt. Discontinue in patients with signs or symptoms of pulmonary toxicity (1).

Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

Related policies
Xospata

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Rydapt may be considered **medically necessary** if the conditions indicated below are met.

Rydapt may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Newly diagnosed acute myeloid leukemia (AML)
    a. FLT3 mutation-positive AML detected by FDA-approved test
    b. Concurrent standard induction therapy with cytarabine and daunorubicin and cytarabine consolidation
2. Aggressive systemic mastocytosis (ASM)
3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
4. Mast cell leukemia (MCL)

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Acute myeloid leukemia (AML)
2. Aggressive systemic mastocytosis (ASM)
3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
4. Mast cell leukemia (MCL)

AND the following:

a. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity	25 mg	672 capsules per 84 days
Duration	12 months	

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Rydapt, a multikinase inhibitor, is indicated for the treatment of FLT3 mutation-positive acute myeloid leukemia and advanced systemic mastocytosis. Patients with FLT3 mutation-positive AML often have worse outcomes compared to patients with other types of AML. Rydapt works by blocking FLT3 receptor signaling and cell proliferation to slow the progression of disease (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Rydapt while maintaining optimal therapeutic outcomes.

References

1. Rydapt [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2023.
2. NCCN Drugs & Biologics Compendium® Midostaurin 2026. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2026.

Policy History

Date	Action
May 2017	Addition to PA
September 2017	Annual review Addition of quantity limits
December 2017	Annual review
June 2018	Annual review
March 2019	Annual review and reference update
June 2020	Annual review and reference update
September 2021	Annual review and reference update
September 2022	Annual review and reference update
March 2023	Annual review and reference update
December 2023	Annual review and reference update
September 2024	Annual review and reference update
December 2024	Annual review and reference update
March 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.