UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 1220-9 |
| Program | Prior Authorization/Notification |
| Medication | Rydapt® (midostaurin) |
| P&T Approval Date | 6/2017, 6/2018, 6/2019, 6/2020, 6/2021, 6/2022, 6/2023, 6/2024. 6/2025 |
| Effective Date | 9/1/2025 |

**1. Background:**

Rydapt® (midostaurin) is a kinase inhibitor indicated for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

Rydapt is also indicated for aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

The National Comprehensive Cancer Network (NCCN) also recommends Rydapt for treatment of myeloid/lymphoid neoplasms with eosinophilia and FGFR1 or FLT3 rearrangements.

**Coverage Information:**
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

**2. Coverage Criteria[a]:**

**A. <u>Patients less than 19 years of age</u>**

1. **Rydapt** will be approved based on the following criterion:

   a. Member is less than 19 years of age

   **Authorization will be issued for 12 months.**

**B. <u>Acute Myeloid Leukemia (AML)</u>**

1. **<u>Initial Authorization</u>**

   a. **Rydapt** will be approved based on **<u>all</u>** of the following criteria:

   (1) Diagnosis of acute myeloid leukemia (AML)

**-AND-**

(2) AML is FLT3 mutation-positive

**-AND-**

(3) Rydapt will be used in combination with standard induction and consolidation therapy

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Rydapt** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rydapt therapy

**Authorization will be issued for 12 months.**

**C. Systemic Mastocytosis**

1. **Initial Authorization**

a. **Rydapt** will be approved based on the following criterion:

(1) Diagnosis of **one** of the following:

(a) Aggressive systemic mastocytosis (ASM)
(b) Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)
(c) Mast cell leukemia (MCL)

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Rydapt** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rydapt therapy

**Authorization will be issued for 12 months.**

**D. Myeloid/Lymphoid Neoplasms**

1. **Initial Authorization**

a. **Rydapt** will be approved based on **both** of the following criteria:

(1) Diagnosis of lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia

**-AND-**

(2) **One** of the following:

(a) Presence of an FGFR1 rearrangement
(b) Presence of an FLT3 rearrangement

**Authorization will be issued for 12 months.**

2. **Reauthorization**

a. **Rydapt** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rydapt therapy.

**Authorization will be issued for 12 months.**

**E. NCCN Recommended Regimens**

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**


1. Rydapt [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; May 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed April 30. 2025.


| Program | Prior Authorization/Notification - Rydapt (midostaurin) |
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| **Change Control** | |
| 6/2017 | New program. |
| 6/2018 | Annual review with no changes to criteria. Updated reference. |
| 6/2019 | Annual review with no changes to criteria. Updated reference. |
| 6/2020 | Annual review with no changes to criteria. Updated reference. |
| 6/2021 | Annual review. Added myeloid/lymphoid neoplasms criteria per NCCN guideline update. Updated references. |
| 6/2022 | Annual review. Revised grammar in criteria with no changes to clinical intent. Updated references. |

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| 6/2023 | Annual review with no changes to clinical criteria. Updated references and added state mandate footnote. |
| 6/2024 | Annual review with no changes to clinical criteria. Updated references. |
| 6/2025 | Annual review. Revised wording in criteria for myeloid/lymphoid neoplasms with no changes to clinical intent. Updated references. |