

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rydapt Prior Authorization Policy

- Rydapt® (midostaurin capsules – Novartis)

REVIEW DATE: 03/06/2024

OVERVIEW

Rydapt, a tyrosine kinase inhibitor, is indicated in adults for the following uses:¹

- **Acute myeloid leukemia, newly diagnosed, that is FMS-like tyrosine kinase 3 (*FLT3*) mutation-positive** as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Limitations of use: Rydapt is not indicated as a single-agent induction therapy for treatment of patients with acute myeloid leukemia.
- **Aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, or mast cell leukemia.**

Guidelines

Rydapt is discussed in the National Comprehensive Cancer Network (NCCN) guidelines:²

- **Acute Myeloid Leukemia:** NCCN guidelines (version 1.2024 – February 28, 2024) recommend Rydapt + standard dose cytarabine and daunorubicin among the treatment options for induction (category 1) and re-induction, consolidation, and post-induction therapy and for relapsed/refractory disease for patients with *FLT3-ITD/TKD* mutation (category 2A).³ It was noted that while Rydapt was not FDA-approved for maintenance therapy, the pivotal trial was designed for consolidation and maintenance for a total of 12 months.
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusion:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend Rydapt for patients with *FGFR1* or *FLT3* rearrangements in chronic phase or blast phase (category 2A).⁴ Rydapt is also recommended for treatment in combination with induction chemotherapy followed by allogeneic hematopoietic cell transplantation (if eligible) for lymphoid, myeloid or mixed lineage neoplasms with eosinophilia and *FGFR1* or *FLT3* rearrangements in blast phase (category 2A).
- **Systemic Mastocytosis:** NCCN guidelines (version 1.2024 – December 21, 2023) recommend Rydapt for the treatment of aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia (all category 2A).⁵

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Rydapt. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rydapt is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A and B):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has *FLT3* mutation-positive disease as detected by an approved test.
2. **Aggressive Systemic Mastocytosis.** Approve for 1 year if the patient is ≥ 18 years of age.
3. **Mast Cell Leukemia.** Approve for 1 year if the patient is ≥ 18 years of age.
4. **Systemic Mastocytosis Associated with Acute Hematologic Neoplasm.** Approve for 1 year if the patient is ≥ 18 years of age.

Other Uses With Supportive Evidence

5. **Myeloid or Lymphoid Neoplasms.** Approve for 1 year if the patient meets the following (A, B, and C):
 - A) Patient is ≥ 18 years of age; AND
 - B) Patient has eosinophilia; AND
 - C) Patient meets one of the following (i or ii):
 - i. Patient has an *FGFR1* rearrangement; OR
 - ii. Patient has an *FLT3* rearrangement.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rydapt is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rydapt® capsules [prescribing information]. East Hanover, NJ: Novartis; May 2023.
2. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 1, 2024. Search term: midostaurin.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2024 – February 28, 2024). © 2024 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 1, 2024.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on March 1, 2024.
5. The NCCN Systemic Mastocytosis Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at <http://www.nccn.org>. Accessed on March 1, 2024.

