

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rydapt Prior Authorization Policy

- Rydapt® (midostaurin capsules – Novartis)

REVIEW DATE: 02/23/2022

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 guidelines from the National Comprehensive Cancer Network (NCCN):²

- **Acute Myeloid Leukemia:** NCCN guidelines (version 1.2022 – December 2, 2021) recommend Rydapt + standard dose cytarabine and daunorubicin among the treatment options for induction, 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 Rydapt for a total of 12 months.
- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Fusion Genes:** NCCN guidelines (version 4.2021 – July 9, 2021) recommend Rydapt for patients with *FGFR1* or *FLT3* rearrangements in chronic 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.
- **Systemic Mastocytosis:** NCCN guidelines (version 3.2021 – July 9, 2021) 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. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rydapt approval requires Rydapt to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are provided for 3 years.

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

Other Uses With Supportive Evidence

5. **Myeloid or Lymphoid Neoplasms.** Approve for 3 years if the patient meets the following criteria (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; November 2021.
 2. The NCCN Drugs & Biologics Compendium. © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 17, 2022. Search term: midostaurin
 3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2022 – December 2, 2021). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 17, 2022
 4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 4.2021 – July 9, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on February 17, 2022.
 5. The NCCN Systemic Mastocytosis Clinical Practice Guidelines in Oncology (version 3.2021 – July 9, 2021). © 2021 National Comprehensive Cancer Network. Available at <http://www.nccn.org>. . Accessed on February 17, 2022.
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