PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Rydapt Prior Authorization Policy
- Rydapt® (midostaurin capsules – Novartis)

REVIEW DATE: 03/08/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 1.2023 – March 3, 2023) 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 for a total of 12 months.

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Fusion Genes:** NCCN guidelines (version 2.2022 – October 18, 2022) 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 2.2022 – October 18, 2022) 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.

- **Rydapt® (midostaurin capsules (Novartis)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following criteria (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. **Systemic Mastocytosis Associated with Acute Hematologic Neoplasm.** Approve for 1 year if the patient is ≥ 18 years of age.

4. **Mast Cell Leukemia.** 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 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 COVERED

- **Rydapt® (midostaurin capsules (Novartis)**

is(are) considered experimental, investigational or unproven for ANY other use(s).

REFERENCES

1. Rydapt® capsules [prescribing information]. East Hanover, NJ: Novartis; November 2021.
2. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023. Search term: midostaurin.
3. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 1.2023 – March 3, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
4. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 2.2022 – October 18, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 7, 2023.
5. The NCCN Systemic Mastocytosis Clinical Practice Guidelines in Oncology (version 2.2022 – October 18, 2022). © 2022 National Comprehensive Cancer Network. Available at http://www.nccn.org. Accessed on March 7, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Acute Myeloid Leukemia**: Criteria for the different types of settings (induction therapy in combination with cytarabine and daunorubicin; or after standard-dose cytarabine induction/reinduction, along with cytarabine and daunorubicin; or post remission or consolidation therapy in combination with cytarabine; or maintenance therapy was removed. **Myeloid or Lymphoid Neoplasms**: The requirement that the patient has eosinophilia was removed from the condition of approval and added into the criteria.	02/23/2022
Selected Revision	**Acute Myeloid Leukemia:** The duration of approval was changed from 3 years to 1 year. **Aggressive Systemic Mastocytosis:** The duration of approval was changed from 3 years to 1 year. **Systemic Mastocytosis Associated with Acute Hematologic Neoplasm:** The duration of approval was changed from 3 years to 1 year. **Mast Cell Leukemia:** The duration of approval was changed from 3 years to 1 year. **Myeloid or Lymphoid Neoplasms:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes.	03/08/2023