

Rydapt (midostaurin)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Rydapt (midostaurin) capsules	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rydapt (midostaurin) may be approved if the following criteria are met:

- I. Individual is diagnosed with one of the following:
 - A. New or relapsed/refractory Acute Myeloid Leukemia (AML) with a confirmed FMS-like tyrosine kinase 3 (FLT3) mutation - positive and test results confirmed; **AND**
 - B. Individual is receiving in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy (Label, NCCN 2A);

OR

- C. For either treatment induction, re-induction, or post-remission therapy in those with FLT3 mutation- positive AML (ITD or TKD mutations) using cytarabine and daunorubicin (NCCN 2A);

OR

- D. For one of the following in those with FLT3 mutation positive AML (ITD or TKD mutations) (NCCN 2A):
 1. Consolidation therapy in combination with high dose cytarabine in those ages less than 60 years old; **OR**
 2. Post-induction therapy in combination with intermediate-dose cytarabine in those ages greater than or equal to 60 years old;

OR

- E. Systemic mastocytosis, including aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) (Label, NCCN 2A);

OR

- F. Myeloid/Lymphoid neoplasms or mixed lineage neoplasms with eosinophilia (NCCN 2A); **AND**
- G. FGFR1 or FLT3 rearrangements.

Requests for Rydapt (midostaurin) may not be approved for the following:

- I. Individual is using as a single-agent induction therapy for the treatment of AML.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 1, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information, visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 1, 2021
 - a. Acute Myeloid Leukemia. V4.2023. Revised July 11, 2023.
 - b. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V1.2023. Revised May 19, 2023.
 - c. Systemic Mastocytosis. V3.2023. Revised June 23, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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