

Market Applicability						
Market	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X

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

OR

 - D. Chronic myelomonocytic leukemia (CMML)-0, CMML-1, or CMML-2 associated systemic mastocytosis (SMA-AHN); **AND**
 - E. Individual has confirmed KIT816V mutation.

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:

CRX-ALL-0601-20

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New Program Date 06/16/2017

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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 20, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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 21, 2020
 - a. Acute Myeloid Leukemia. V3.2020. Revised December 23, 2019.
 - b. Myelodysplastic Syndromes. V2.2020. Revised February 28, 2020.
 - c. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. V1.2020. New July 15, 2020.
 - d. Systemic Mastocytosis. V1.2020. Revised May 21, 2020.

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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