

## PHARMACY POLICY STATEMENT

### Ohio Medicaid

DRUG NAME	Rydapt (midostaurin)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT – 60 for 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

Rydapt (midostaurin) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

#### ACUTE MYELOID LEUKEMIA (AML)

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member is FLT3 mutation-positive as detected by an FDA-approved test (LeukoStrat® CDx FLT3 Mutation Assay); AND
3. Medication is used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation (Note: Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML); AND
4. Member who progresses to hematopoietic stem cell transplantation (SCT) must stop taking Rydapt.
5. **Dosage allowed:** 50 mg orally twice daily with food.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved.***

#### AGGRESSIVE SYSTEMIC MASTOCYTOSIS (ASM), SYSTEMIC MASTOCYTOSIS WITH ASSOCIATED HEMATOLOGICAL NEOPLASM (SM-AHN), OR MAST CELL LEUKEMIA (MCL)

For **initial** authorization:

1. Member is 18 years of age or older; AND
2. Member does not have any of the following:
  - a) Serum creatinine > 2.0 mg/dl;
  - b) Hepatic transaminases > 2.5 x upper limit of normal (ULN) or > 5 x ULN if disease-related, total bilirubin > 1.5 x ULN or > 3 x ULN if disease-related;
  - c) QTc > 450 msec;
  - d) Cardiovascular disease including left-ventricular ejection fraction < 50%, or any pulmonary infiltrates;

- e) Acute-stage or life-threatening AHN.
- 3. **Dosage allowed:** 100 mg orally twice daily with food.

***If member meets all the requirements listed above, the medication will be approved for 6 months.***

For **reauthorization**:

- 1. Member must be in compliance with all other initial criteria; AND
- 2. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

***If member meets all the reauthorization requirements above, the medication will be approved.***

**CareSource considers Rydapt (midostaurin) not medically necessary for the treatment of the diseases that are not listed in this document.**

DATE	ACTION/DESCRIPTION
06/27/2017	New policy for Rydapt created.

References:

- 1. Rydapt [package insert]. East Hanover, NJ; Novartis Pharmaceuticals Corporation: April, 2017.

Effective date: 09/01/2017

Revised date: 06/27/2017