Rydarpt (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: Rydarpt 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 Rydarpt.
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;
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.

<table>
<thead>
<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>06/27/2017</td>
<td>New policy for Rydapt created.</td>
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References:

Effective date: 09/01/2017
Revised date: 06/27/2017