CareSource

PHARMACY POLICY STATEMENT **Indiana 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 **NOT** MEDICALLY NECESSARY	Click Here

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: 01/01/2018
Revised date: 06/27/2017