UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Rydapt

Program	Prior Authorization
Medication	Rydapt™ (midostaurin)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2017
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Rydapt™ (midostaurin) is a kinase inhibitor indicated for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 mutation-positive as detected by an FDA-approved test, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation. Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML. Rydapt is also indicated for aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).[1]

2. Coverage Criteria:

A. Acute Myeloid Leukemia (AML)

1. Initial Authorization

a. **Rydapt** will be approved based on **all** of the following criteria:

(1) Diagnosis of acute myeloid leukemia (AML)

-AND-

(2) AML is FLT3 mutation-positive

-AND-

(3) Rydapt will be used in combination with standard induction and consolidation therapy

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rydapt** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rydapt therapy

Authorization will be issued for 12 months.

B. Systemic Mastocytosis

1. Initial Authorization

a. **Rydapt** will be approved based on the following criterion:

(1) Diagnosis of **one** of the following:

(a) Aggressive systemic mastocytosis (ASM)
(b) Systemic mastocytosis with associated hematologic neoplasm (SM-AHN)
(c) Mast cell leukemia (MCL)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rydapt** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Rydapt therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

1. Initial Authorization

a. **Rydapt** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Rydapt** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Rydapt therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Rydapt [package insert]. East Hanover, NJ: Novartis Pharmaceutical Corporation; March 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May12, 2020.

Program	Prior Authorization – Rydapt (midostaurin)
Change Control	
Date	Change
6/2017	New program.
6/2018	Added NCCN recommended regimen criteria. Updated references.
6/2019	Annual review with no changes to criteria. Updated references.
6/2020	Annual review. Updated References. Added Additional Clinical Rules section.