Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Rydapt (midostaurin)

Policy Number: 5.01.637
Origination: 10/2017
Last Review: 10/2018
Next Review: 10/2019

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Rydapt (midostaurin) when it is determined to be medically necessary because the following criteria have been meet.

When Policy Topic is covered

Rydapt may be considered **medically necessary** in patients 18 years or older with newly diagnosed acute myeloid leukemia (AML), aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) and if the conditions indicated below are met.

The patient must have ONE of the following:

1. Newly diagnosed acute myeloid leukemia (AML)
    a. FLT3 mutation-positive AML detected by FDA-approved test
    b. Concurrent standard induction therapy with cytarabine and daunorubicin and cytarabine consolidation
2. Aggressive systemic mastocytosis (ASM)
3. Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
4. Mast cell leukemia (MCL)

When Policy Topic is not covered

Rydapt is considered **investigational** in patients below 18 years of age and for all other indications.

Limitations of Use: (1)

1. Rydapt is not indicated as a single-agent induction therapy for the treatment of patients with AML.

Considerations

Rydapt requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Background

Rydapt is an oral cancer agent that inhibits multiple receptor tyrosine kinases. Rydapt is indicated for the treatment of acute myeloid leukemia (AML), an aggressive cancer of the blood and bone, and advanced systemic mastocytosis. Some patients with AML have a gene mutation in the FLT3 cell-surface receptor which can result in faster disease progression, higher relapse rate, and lower survival rates than other forms of AML. Rydapt works by blocking the FLT3 receptor signaling and cell proliferation and inducing apoptosis of certain leukemic cells (1).

Regulatory Status
FDA-approved indication: Rydapt is a kinase inhibitor indicated for the treatment of adult patients with:

1. 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 (1).

2. Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL) (1).

3. Treatment of adult patients with mast cell leukemia (MCL).

Rydapt may cause fetal harm when administered to a pregnant women. Verify the pregnancy status of females of reproductive potential within 7 days prior to initiating therapy. Advise females and males with female partners to use effective contraception during treatment with Rydapt and for 4 months after the last dose (1).

Cases of interstitial lung disease and pneumonitis, some fatal, have occurred in patients taking Rydapt. Discontinue in patients with signs or symptoms of pulmonary toxicity (1).

Safety and efficacy in pediatric patients below the age of 18 have not been established (1).

Rationale

Rydapt, a multikinase inhibitor, is indicated for the treatment of FLT3 mutation-positive acute myeloid leukemia and advanced systemic mastocytosis. Patients with FLT3 mutation-positive AML often have worse outcomes compared to patients with other types of AML. Rydapt works by blocking FLT3 receptor signaling and cell proliferation to slow the progression of disease (1). Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Rydapt while maintaining optimal therapeutic outcomes.

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

Billing Coding/Physician Documentation Information

Rydapt is considered a pharmacy benefit, specialty

Additional Policy Key Words

5.01.637

Policy Implementation/Update Information

10/2017	New policy titled Rydapt (midostaurin)
10/2018	No changes made