Pharmacy Prior Authorization Form

Fax completed form to: 877.974.4411 toll free, or 616.942.8206

This form applies to: ☒ **Commercial (Traditional)** ☒ **Commercial Individual (Optimized)** ☐ **Medicaid**

This request is: ☐ **Urgent** (life threatening) ☐ **Non-Urgent** (standard review)

Urgent means the standard review time may seriously jeopardize the life or health of the patient or the patient's ability to regain maximum function.

Rydapt® (midostaurin)

Member

Last Name: _____ First Name: _____

ID #: _____ DOB: _____ Gender: _____

Primary Care Physician: _____

Requesting Provider: _____ Prov. Phone: _____ Prov. Fax: _____

Provider Address: _____

Provider NPI: _____ Contact Name: _____

Provider Signature: _____ Date: _____

Product Information

☐ New request ☐ Continuation request

Drug product: ☐ Rydapt 25 mg capsule

Start date (or date of next dose): _____

Date of last dose (if applicable): _____

Dosing frequency: _____

Drug cost information

The wholesale acquisition cost (WAC) for Rydapt is $133.84 per capsule. This correlates to an estimated annual cost of treatment of $195,406 for AML and $390,813 for advanced SM.

Precertification Requirements

Initiation Criteria

Before this drug is covered, the patient must meet the following requirements:

1. Patient must have one of the following diagnoses:
   - Acute myeloid leukemia (AML)
     - Acute promyelocytic leukemia (APL) is not a covered indication
   - Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

2. For AML, the patient meets all of the following:
   - Newly diagnosed AML
   - Documentation of FLT3 mutation-positive as detected by an FDA-approved test
   - Use with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy
   - 18 years or older

3. For ASM, SM-AHN, and MCL, the patient meets all of the following:
   - 18 years or older

All fields must be complete and legible for review. Your office will receive a response via fax. No changes made since 09/2018

Last reviewed 01/2019

Continuation Criteria for ASM, SM-AHN, and MCL:

The patient meets *one* of the following requirements:

1. Complete resolution or > 20% improvement in one or more C-findings without progression in other C-findings (*see table below*) AND a sustained response to therapy for at least 8 weeks (*based on Study 2 -D2201*)

   OR

2. Complete remission as observed on bone marrow biopsy

C-findings (based on modified Valent criteria for primary Study 2 - D2201)

Neutropenia (ANC < 1000/uL)
Anemia (Hgb < 10g/dL)
Thrombocytopenia (platelet count <100,000/uL)
Transfusion-dependent anemia; Transfusion-dependent thrombocytopenia
Elevated ALT, AST, total bilirubin
Hypoalbuminemia
Palpable splenomegaly with hypersplenism-thrombocytopenia (platelet count < 100,000/uL)
Malabsorption with hypoalbuminemia and/or weight loss

Dosage Limit

For ASM, SM-AHN, and MCL: Rydapt will be limited to # 60 tablets every 30 days. Initial requests are approved for 6 months. Continuation requests are approved in 12 months intervals.

For AML: Rydapt will be limited to #56 tablets every 21 days for a total of 6 cycles (e.g., total tablet count of #336).

Note: Authorization for indications, dosing, or a route of administration not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the appropriateness of the drug, the dosing of the drug, or the route of administration to be used for the identified indication.

Priority Health Precertification Documentation

Initiation Criteria

A. What condition is this drug being requested for?

- ☐ Acute myeloid leukemia (not including acute promyelocytic leukemia)
- ☐ Advanced systemic mastocytosis
  - ☐ Aggressive systemic mastocytosis (ASM)
  - ☐ Systemic mastocytosis with associated hematological neoplasm (SM-AHN)
  - ☐ Mast cell leukemia (MCL)
- ☐ *Other – the patient's condition is:* _____

Rationale for use: _____

For Acute Myeloid Leukemia (AML)

A. Is the patient newly diagnosed?

- ☐ Yes
- ☐ No. *Rationale for use:* _____

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Last reviewed 01/2019

B. Does the patient have FLT3 mutation-positive disease as detected by an FDA-approved test?

- ☐ Yes
- ☐ No. *Rationale for use:* _____

C. Is Rydapt being used in combination with standard cytarabine and daunorubicin induction and/or cytarabine consolidation chemotherapy?

- ☐ Yes
- ☐ No. *Rationale for use:* _____

Continuation Criteria – ASM, SM-AHN, and MCL

A. Has the patient had complete remission as observed on bone marrow biopsy?

- ☐ Yes.
- ☐ No.

B. Has the patient had a complete resolution or a greater than 20% improvement in one or more C-findings?

- ☐ Yes.
- ☐ No. *Rationale for use:* _____

B. Has the patient had progression in one or more C-findings?

- ☐ Yes. *Rationale for use:* _____
- ☐ No. If no, go to question D.

D. Has the patient sustained a response to Rydapt therapy for at least 8 weeks?

- ☐ Yes
- ☐ No. *Rationale for use:* _____

Additional information

References:

1. Kasamon, Yvette. Center for Drug Evaluation and Research: Medical Review(s). NDA 207997, Orig 1. Rydapt (Midostaurin). Available at: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2017/207997Orig1Orig2s000MedR.pdf
2. RYDAPT® [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017

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Last reviewed 01/2019