

Reference number
1817-A

## SPECIALTY GUIDELINE MANAGEMENT

### RYDAPT (midostaurin)

#### POLICY

##### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

##### FDA-Approved Indications

- A. Rydapt is indicated, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by a FDA approved test.

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

- B. Rydapt is indicated for the treatment of adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).

All other indications are considered experimental/investigational and are not covered benefits.

##### II. CRITERIA FOR INITIAL APPROVAL

##### A. Acute Myeloid Leukemia (AML)

Authorization of 12 months may be granted to adult members for the treatment of newly diagnosed FLT3 mutation-positive AML when Rydapt is/was used in combination with standard cytarabine with daunorubicin or idarubicin induction followed by cytarabine consolidation chemotherapy.

##### B. Aggressive Systemic Mastocytosis (ASM), Systemic Mastocytosis with associated hematological neoplasm (SM-AHN), and Mast Cell Leukemia (MCL)

Authorization of 12 months may be granted to adult members for the treatment of ASM, SM-AHN, or MCL.

##### III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

##### IV. REFERENCES

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

2. National Comprehensive Cancer Network. The NCCN Drugs & Biologics Compendium. <http://www.nccn.org>. Accessed September 6, 2017.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Acute Myeloid Leukemia. Version 3.2017. [http://www.nccn.org/professionals/physician\\_gls/pdf/aml.pdf](http://www.nccn.org/professionals/physician_gls/pdf/aml.pdf). Accessed September 6, 2017.