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.

A. FDA-Approved Indications

1. 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 an FDA approved test.

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

2. 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).

B. Compendial Uses

1. Acute Myeloid Leukemia (AML): Relapsed/refractory disease, post-induction therapy, re-induction of residual disease, and maintenance therapy
2. Myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions

All other indications are considered experimental/investigational and are not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: Medical record documentation of FLT3 mutation or FGFR1 rearrangement (where applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Acute myeloid leukemia (AML)
Authorization of 12 months may be granted for the treatment of FLT3 mutation-positive AML when it is not used as a single-agent for induction therapy.

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 for the treatment of ASM, SM-AHN, or MCL as a single agent.

C. Myeloid/Lymphoid Neoplasms with eosinophilia and tyrosine kinase gene fusions
Authorization of 12 months may be granted for the treatment of myeloid and/or lymphoid neoplasms with eosinophilia with a FGFR1 or FLT3 rearrangement in the chronic phase or blast phase.

IV. CONTINUATION OF THERAPY

A. Acute myeloid leukemia (AML)
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity.

B. Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), mast cell leukemia (MCL), myeloid/lymphoid neoplasms with eosinophilia and tyrosine kinase gene fusions
Authorization of 12 months may be granted for continued treatment in members requesting reauthorization when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Rydapt [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2023.
2. The NCCN Drugs & Biologics Compendium®. © 2024 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed January 3, 2024.