

Midostaurin (RYDAPT®)

Criteria for Use

June 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTERnet](#) or [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive midostaurin.

- Hypersensitivity to midostaurin or any of the excipients
- Inability to swallow whole capsules
- Pregnancy (known pregnancy or positive pregnancy test)
- Lactating

Inclusion Criteria

One of the following must be fulfilled to meet criteria.

- Newly diagnosed FLT3 mutation positive Acute Myeloid Leukemia (AML) and eligible for standard induction and consolidation chemotherapy regimens
- Diagnosis of Aggressive Systemic Mastocytosis (ASM), Indolent Systemic Mastocytosis (ISM), Systemic Mastocytosis with Associated Hematologic Neoplasm (SM-AHN) or Mast Cell Leukemia (MCL)

Additional Inclusion Criteria *The answers to the following must be fulfilled to meet criteria:*

- Care for the condition provided by VA or VA Community Care hematology/oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group (ECOG) performance status 0 - 3

Additional Inclusion Criteria *Select if applicable:*

- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risk vs. benefit of taking midostaurin if they were to become pregnant.
- For patients who can become pregnant and patients with partners who can become pregnant: Counsel on effective contraception use during treatment and for 4 months following the last dose.

Other Justification

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