Clinical Policy Title:	midostaurin
Policy Number:	RxA.271
Drug(s) Applied:	Rydapt®
Original Policy Date:	02/07/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Acute Myeloid Leukemia (must meet all):

1. Diagnosis of acute myeloid leukemia;
2. Member has FLT3 mutation as detected by an FDA-approved test;
3. If request is for induction therapy, prescribed in combination with cytarabine and daunorubicin;
4. If request is for consolidation or post induction therapy, prescribed in combination with cytarabine.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Advanced Systemic Mastocytosis (must meet all):

1. Diagnosis of one of the following (a, b, or c):
   a. Aggressive systemic mastocytosis;
   b. Systemic mastocytosis with associated hematologic neoplasm;
   c. Mantle cell lymphoma.

Approval Duration

All Lines of Business (except Medicare): 6 months

C. Myeloid/lymphoid neoplasm Off-Label (must meet all):

1. Diagnosis of myeloid/lymphoid neoplasm with eosinophilia and FGFR1 or FLT3 rearrangements in blast phase.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Acute Myeloid Leukemia Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Systemic Mastocytosis Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mastocytosis.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Myelodysplastic Syndromes. Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mds.pdf. Accessed August 28, 2024.
4. National Comprehensive Cancer Network. Myeloid/lymphoid Neoplasm with Eosinophilia and Tyrosine Kinase Fusion Gene. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Rephrased initial therapy criteria I.A.4. and included “as detected by FDA approved test”Removed initial therapy criteria I.A.7.b. and I.B.4.b. 3. Continued therapy criteria II.A.1. rephrased to “Member is currently receiving midostaurin that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy”. 4. Length of duration for initial and continued therapy was updated. 5. References were updated.	07/10/2020	09/14/2020
Policy was reviewed: 1. Continued therapy II.A.1 criteria was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance...”. 2. References were updated.	04/01/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, 1.C: Updated to include approval criteria for indication Myeloid/lymphoid neoplasm. 2. References were reviewed and updated.	01/25/2022	04/18/2022
Policy was reviewed:	12/30/2022	04/13/2023

1. Initial Approval Criteria I.A.6: Updated to add post induction therapy. 2. References were reviewed		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024