Clinical Policy Title:	gilteritinib
Policy Number:	RxA.317
Drug(s) Applied:	Xospata®
Original Policy Date:	02/07/2020
Last Review Date:	08/28/2024
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 relapsed or refractory acute myeloid leukemia;
2. Diagnosis is positive for FLT3 mutation.

Approval Duration

All Lines of Business (except Medicare): 6 months

B. Myeloid/Lymphoid Neoplasms with Eosinophilia and TK Fusion Genes (off Label) (must meet all)**:**

1. Diagnosis of myeloid/lymphoid neoplasms with eosinophilia and TK fusion genes (rearrangement of PDGFRA, PDGFRB or FGFR1);
2. Diagnosis is positive for FLT3 mutation.

Approval duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. All Indication 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. Ravandi F, Alattar ML, Grunwald MR, et al. Phase 2 study of azacytidine plus sorafenib in patients with acute myeloid leukemia and FLT-3 internal tandem duplication mutation. Blood 2013;121(23):4655-62. Available at: https://ashpublications.org/blood/article/121/23/4655/31475/Phase-2-study-of-azacytidine-plus-sorafenib-in. Accessed August 28, 2024.
2. 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.
3. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date

Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Policy was reviewed: Policy title table was updated: Clinical Policy Title was updated to ”gilteritinib". Drug(s) Applied was updated to "Xospata®". Line of Business Policy Applies to was updated to "All". 2. Clinical policy was updated: Approval duration was updated for both Initial and Continued Approval Criteria; Continued Approval was rephrased to "Currently receiving medication that has been authorized by RxAdvance". 3. References were updated.	07/13/2020	09/14/2020
Policy was reviewed: 1. Initial and continued therapy approval criteria was created for ‘’Myeloid/Lymphoid Neoplasms with Eosinophilia and TK Fusion Genes’’ (off label use). 2. Approval duration for HIM was removed. 3. References were updated.	03/31/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria I.B2: Updated to remove Documentation of the presence of TK Fusion Genes and Hypereosinophilia (HE) eosinophil count >1.5 x109 /L; and updated to add Documentation of the presence of an FLT3 mutation. 2. Initial Approval Criteria I.B.5: Updated to remove Failure of imatinib monotherapy, unless contraindicated or clinically significant adverse effects are experienced. 3. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 4. References were reviewed and updated.	01/28/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	01/12/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions.	08/28/2024	9/13/2024

4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Reauthorization criteria for all the diagnosis merged under “All Indications in Section I”. 6. Removed reauthorization requirement for positive response to therapy. 7. Updated approval duration verbiage. 8. References were reviewed and updated.		