Clinical Policy Title:	gilteritinib
Policy Number:	RxA.317
Drug(s) Applied:	Xospata®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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 (AML);
2. Documentation of the presence of an FLT3 mutation;
3. Prescribed by or in consultation with an oncologist or hematologist;
4. Age is ≥ 18 years;
5. Dose does not exceed 120 mg per day;

Approval Duration
Commercial: 6 months
Medicaid: 6 months

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

1. Diagnosis Myeloid/Lymphoid Neoplasms with Eosinophilia (MLN-Eo) and TK Fusion Genes (rearrangement of PDGFRA, PDGFRB or FGFR1);
2. Documentation of the presence of an FLT3 mutation;
3. Prescribed by or in consultation with an oncologist or hematologist;
4. Age is ≥ 18 years;
5. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Acute Myeloid Leukemia (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Xospata® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, dose does not exceed 120 mg per day;

Approval Duration
Commercial: 6 months

Medicaid: 6 months

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

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 6 months
Medicaid: 6 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 January 10, 2023.
2. National Comprehensive Cancer Network. Acute Myeloid Leukemia. Version 3.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed January 10, 2023.
3. National Comprehensive Cancer Network. Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes. Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/mlne.pdf. Accessed January 10, 2023.

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