PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xospata Prior Authorization Policy
- Xospata® (gilteritinib tablets – Astellas)

REVIEW DATE: 01/17/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Xospata, an inhibitor of tyrosine kinases including FMS-like tyrosine kinase 3 (*FLT3*), is indicated for the treatment of relapsed or refractory **acute myeloid leukemia** in adults with an *FLT3* mutation as detected by an FDA-approved test.[1]

Guidelines

Xospata is discussed in the National Comprehensive Cancer Network (NCCN) guidelines:

- **Acute Myeloid Leukemia:** Guidelines (version 6.2023 – October 24, 2023) recommend Xospata in patients with relapsed or refractory disease and *FLT3*-internal tandem duplication (*FLT3-ITD*) or *FLT3*-tyrosine kinase domain (*FLT3-TKD*) mutation (category 1 for both).[2] Xospata is also recommended as treatment induction for patients with a *FLT3* mutation who are not candidates for intensive induction therapy (category 2B); it is also recommended for follow-up after treatment induction and consolidation therapy in specific situations (category 2B) and as maintenance therapy for patients who are post-allogeneic hematopoietic stem cell transplantation in remission with a *FLT3* mutation (category 2B).

- **Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes:** Guidelines (version 1.2024 – December 21, 2023) recommend Xospata for the treatment of myeloid/lymphoid neoplasms with eosinophilia and *FLT3* rearrangement in chronic phase or blast phase (category 2A). Xospata is also recommended in combination with acute lymphocytic leukemia- or acute myeloid leukemia-type induction chemotherapy followed by allogeneic hematopoietic stem cell transplantation (if eligible) for lymphoid, myeloid, or mixed lineage neoplasms with eosinophilia and *FLT3* rearrangement in blast phase (category 2A).[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Xospata. All approvals are provided for the duration noted below.

- **Xospata® (gilteritinib tablets (Astellas)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Acute Myeloid Leukemia.** Approve for 1 year if the patient meets the following (A, B, and C).
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed or refractory disease; AND
   C) Disease is *FLT3*-mutation positive as detected by an approved test.

Other Uses with Supportive Evidence

2. **Myeloid/Lymphoid Neoplasms.** Approve for 1 year if the patient meets the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has eosinophilia; AND
   C) Disease is *FLT3*-mutation positive as detected by an approved test.

CONDITIONS NOT COVERED

- **Xospata® (gilteritinib tablets (Astellas)**

is(are) considered experimental, investigational, or unproven for ANY other use(s).

REFERENCES

1. Xospata® tablets [prescribing information]. Northbrook, IL: Astellas Pharma; January 2022.
2. The NCCN Acute Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 6.2023 – October 24, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 12, 2024.

3. The NCCN Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Fusion Genes Clinical Practice Guidelines in Oncology (version 1.2024 – December 21, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on January 12, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria change.	01/04/2023
Annual Revision	No criteria change.	01/17/2024