

Xospata® (gilteritinib) (Oral)

Document Number: IC-0418

Last Review Date: 02/04/2020

Date of Origin: 01/03/2019

Dates Reviewed: 01/2019, 02/2020

I. Length of Authorization

- Coverage will be provided for six months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Xospata 40 mg tablets: 3 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 120 mg per day

III. Initial Approval Criteria ^{1,2,3,4}

Coverage is provided in the following conditions:

Universal Criteria

- Patient is at least 18 years old; **AND**
- Not used in combination with other FMS-like tyrosine kinase (FLT)-inhibitors (e.g., midostaurin, sorafenib, etc.); **AND**
- Not used in combination with P-glycoprotein and strong CYP3A inducers (e.g., rifampin, etc.); **AND**
- Patient does not have active, uncontrolled central nervous system (CNS) leukemia; **AND**
- Patient has had a baseline electrocardiogram (ECG); **AND**

Acute Myeloid Leukemia (AML) †

- Patient must be diagnosed with AML (disease that is de novo or secondary to myelodysplastic syndrome[MDS] only); **AND**
- Patient's disease is FMS-like tyrosine kinase-3 (FLT3) mutation-positive (FLT3+), with ITD or ITD/TKD variant mutations (*excludes pure TKD mutations*), as confirmed by an FDA-cleared, or CLIA-compliant, test*; **AND**

- Used as single-agent therapy; **AND**
 - Patient has a hematological relapse after achieving complete remission (CR), complete remission with incomplete hematologic recovery (CRi), or complete remission with incomplete platelet recovery (CRp) on initial therapy; **OR**
 - Patient has refractory disease to initial induction therapy as defined as not having achieved a CR, CRi, or CRp.

**<http://www.fda.gov/companiondiagnostics>*

† FDA Approved Indication(s); ‡ Compendia recommended indication(s)

IV. Renewal Criteria ¹

Coverage may be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: posterior reversible encephalopathy syndrome (PRES), prolonged QT-interval (i.e., interval \geq 500 ms and/or interval prolongation with signs and symptoms of severe arrhythmia), pancreatitis, anaphylaxis, etc.; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] (i.e. morphologic, cytogenetic or molecular complete response CR), complete hematologic response or a partial response by CBC, bone marrow cytogenetic analysis, QPCR, or FISH

V. Dosage/Administration

Indication	Dose
AML	Take 120 mg (three 40 mg tablets) orally once daily (for at least six months) until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code:

- J8999: Prescription drug, oral, chemotherapeutic, nos
- C9399: Unclassified drugs or biologics

NDC:

- Xospata 40 mg tablets: 00469-1425-xx

VII. References

1. Xospata [package insert]. Northbrook, IL; Astellas Pharma US, Inc. Updated May 2019. Accessed December 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) gilteritinib. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2019.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Acute Myeloid Leukemia. Version 3.2020. National Comprehensive Cancer Network, 2020. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2019.
4. Perl AE, Martinelli G, Cortes JE, et al. Gilteritinib or Chemotherapy for Relapsed or Refractory FLT3-Mutated AML. N Engl J Med. 2019 Oct 31;381(18):1728-1740. doi: 10.1056/NEJMoa1902688.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C92.00	Acute myeloblastic leukemia not having achieved remission
C92.02	Acute myeloblastic leukemia, in relapse
C92.50	Acute myelomonocytic leukemia not having achieved remission
C92.52	Acute myelomonocytic leukemia, in relapse
C92.60	Acute myeloid leukemia with 11q23-abnormality not having achieved remission
C92.62	Acute myeloid leukemia with 11q23-abnormality in relapse
C92.A0	Acute myeloid leukemia with multilineage dysplasia not having achieved remission
C92.A2	Acute myeloid leukemia with multilineage dysplasia, in relapse
C93.00	Acute monoblastic/monocytic leukemia not having achieved remission
C93.02	Acute monoblastic/monocytic leukemia, in relapse
C94.00	Acute erythroid leukemia not having achieved remission
C94.02	Acute erythroid leukemia, in relapse
C94.20	Acute megakaryoblastic leukemia not having achieved remission
C94.22	Acute megakaryoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC