GILTERITINIB

Generic	Brand	HICL	GCN	Exception/Other
GILTERITINIB FUMARATE	XOSPATA	45506		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of relapsed or refractory acute myeloid leukemia (AML) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

   If yes, **approve for 12 months by HICL with a quantity limit of #3 tablets per day.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **GILTERITINIB (Xospata)** requires a diagnosis of relapsed or refractory acute myeloid leukemia (AML). In addition, the following criteria must be met:
   - The patient is 18 years of age or older
   - The patient has FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test

RATIONALE
For further information, please refer to the Prescribing Information and/or Drug Monograph for Xospata.

REFERENCES
- Xospata [Prescribing Information]. Northbrook, IL: Astellas Pharma US, Inc.; November 2018

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/19
Created: 03/19
Client Approval: 03/19
P&T Approval: 01/19