# SPECIALTY GUIDELINE MANAGEMENT

# XOSPATA (gilteritinib)

#### POLICY

#### I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### **FDA-Approved Indications**

Xospata is indicated for the treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test.

All other indications are considered experimental/investigational and are not a covered benefit.

# **II. CRITERIA FOR INITIAL APPROVAL**

## Acute Myeloid Leukemia (AML)

Authorization of 12 months may be granted to adult members for the treatment of FLT3 mutation-positive relapsed or refractory AML.

## **III. CONTINUATION OF THERAPY**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

#### **IV. REFERENCES**

1. Xospata [package insert]. Northbrook, IL: Astellas Pharma Inc.; November 2018.

Xospata

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