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 not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review (new starts only):

- medical record documentation of FLT3 mutation as detected by an FDA-approved test

III. CRITERIA FOR INITIAL APPROVAL

Acute Myeloid Leukemia (AML)
Authorization of 12 months may be granted for the treatment of FLT3 mutation-positive relapsed or refractory AML when the requested medication is used as a single-agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who have not experienced disease progression or an unacceptable toxicity.

V. REFERENCES