

XOSPATA (gilteritinib)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory acute myeloid leukemia (AML)

AND ALL of the following:

- 1. Documented FLT3 mutation as detected by an FDA-approved test
- 2. Prescriber agrees to monitor electrocardiogram (ECG), complete blood count (CBC), and creatine phosphokinase
- Females of reproductive potential only: patient will be advised to use effective contraception during therapy and for at least 6 months after the last dose
- 4. Males with female partners of reproductive potential only: patient will be advised to use effective contraception during therapy and for at least 4 months after the last dose

Prior - Approval Limits

Quantity 270 tablets per 90 days

Duration 6 months

Prior – Approval Renewal Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Relapsed or refractory acute myeloid leukemia (AML)

AND ALL of the following:

- 1. NO disease progression or unacceptable toxicity
- 2. Prescriber agrees to monitor electrocardiogram (ECG), complete blood



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- count (CBC), and creatine phosphokinase
- 3. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for at least 6 months after the last dose
- 4. Males with female partners of reproductive potential only: patient will be advised to use effective contraception during therapy and for at least 4 months after the last dose

Prior - Approval Renewal Limits

Same as above