Gilteritinib (Xospata)
Criteria for Use
May 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at *www.pbm.va.gov* or *http://vaww.pbm.va.gov* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive gilteritinib.

- ☐ Unable to comply with recommended laboratory monitoring
- ☐ Baseline QTc > 500 msec
- ☐ Patient is on chronic therapy with a combined P-gp and strong CYP3A inducer (e.g. rifampin)
- ☐ Severe renal impairment (CrCl <30 ml/min) - has not been studied
- ☐ Severe hepatic impairment (Child-Pugh Class C) – has not been studied
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Prescriber is a VA/VA Community Care hematology/oncology provider
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with FMS-like tyrosine kinase 3 (FLT3) mutation (i.e. ITD or TKD) as detected by an FDA-approved test
- ☐ Medication profile reviewed for concomitant CYP3A inhibitors which may increase gilteritinib concentrations and potential toxicity
- ☐ Medication profile reviewed for chronic SSRI therapy (e.g. escitalopram, fluoxetine, sertraline) as gilteritinib may reduce their effectiveness
- ☐ For female patients of child-bearing potential: provided counseling on effective contraception and risk vs. benefit of treatment. Continue contraception for at least 6 months after the final dose
- ☐ For male patients with partners of child-bearing potential: provided counseling on effective contraception and potential risk vs. benefit of treatment. Continue contraception for at least 4 months after the final dose

Updated version may be found at *PBM INTERnet* or *PBM INTRAnet*

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