

Xospata (gilteritinib)
Effective 01/01/2021

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Gilteritinib is a tyrosine kinase inhibitor which inhibits multiple tyrosine kinases, such as FMS-like tyrosine kinase 3 (FLT3). Gilteritinib inhibits FLT3 receptor signaling and proliferation in cells expressing FLT3 (including FLT3-ITD), tyrosine kinase domain mutations (TKD) FLT3-D835Y and FLT3-ITD-D835Y; it induces apoptosis in FLT3-ITD-expressing leukemia cells.

Coverage Guidelines

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member is being treated for a FLT3 mutation-positive relapsed or refractory Acute Myeloid Leukemia (AML).
2. Age \geq 18 years
3. Prescriber is a hematologist/oncologist
4. Appropriate dosing
5. **ONE** of the following:
 - a. Member has received at least one line of treatment (see appendix below)
 - b. Member has relapsed or refractory disease

Continuation of Therapy

Authorization may be granted for continued treatment in members requesting reauthorization for the treatment of FLT3 mutation-positive relapsed or refractory AML who have not experienced disease progression or an unacceptable toxicity.

Limitations

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1. Approvals will be granted for 12 months.
2. The following quantity limits apply:

Xospata	90 tablets per 30 days
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- Requests for over the quantity limit should be reviewed against the Global Quantity Limit criteria.

Appendix:

Depending on the patient’s age and risk status, a variety of treatments could be used for first-line therapy of acute myeloid leukemia.

Patients less than 60 years of age may receive the following treatment for induction therapy before receiving consolidation therapy:

- Cytarabine with idarubicin or daunorubicin
- Cytarabine with daunorubicin and gemtuzumab ozogamicin
- Cytarabine with daunorubicin and midostaurin (FLT3-mutated)
- Cytarabine with daunorubicin and cladribine
- Daunorubicin and cytarabine
- High-dose cytarabine with daunorubicin or idarubicin
- Fludarabine and idarubicin

Patients who are 60 years of age or older may receive the following treatment for induction therapy before receiving consolidation therapy:

- Cytarabine with daunorubicin and gemtuzumab ozogamicin (CD33-positive)
- Cytarabine with idarubicin or daunorubicin or mitoxantrone
- Daunorubicin and cytarabine
- Cytarabine with daunorubicin and midostaurin (FLT3-mutated)
- Venetoclax and decitabine
- Venetoclax and azacitidine
- Venetoclax and cytarabine
- Azacitidine
- Decitabine

References

1. Xospata [package insert]. Northbrook, IL: Astellas Pharma Inc.; May 2019.
2. The NCCN Drugs & Biologics Compendium 2019 National Comprehensive Cancer Network, Inc. <http://www.nccn.org>. Accessed July 17, 2019.
3. Lexicomp [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed (June 2020).

Review History

2020 – Transitioned SGM to Custom Template

September 30, 2020: Update to meet the MassHealth partial unified formulary requirements; added appendix for first-line AML treatment, separate criteria from the Commercial line of business.



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