Xospata (gilteritinib)
Effective 01/01/2021

Plan	☐ MassHealth ☒ MassHealth (PUF) ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ 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 ≥ 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

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

Xospata	90 tablets per 30 days

   - 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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