Mass General Brigham
Health Plan

New to Market
Effective 04/01/2023

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	N/A		
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

New-to-market (NTM) medications have a review process prior to being added to our formulary. Medications will be evaluated by Pharmacy and Therapeutics Committee and Drug Coverage Committee to analyze current literature to determine benefits and risks of these medications.

Coverage Guidelines

Approval of a new-to-market medication may be approved when the following criteria is met:

1. The requested drug is being used for an FDA-approved indication that is covered under the member's plan documents OR for a recognized off-label use of an FDA-approved drug used in the treatment of cancer or HIV/AIDS
2. ONE of the following is met:
    a. Documentation from the prescriber the patient had an inadequate treatment response or intolerance to ALL formulary alternatives for the given diagnosis (or to at least one agent within each of a given class of agents when more than one class is available for the diagnosis)
    b. The patient has a contraindication to all formulary alternatives
    c. This is the only FDA-approved product for the patient's diagnosis and documentation from the prescriber showing that all other available lines of treatment consistent with generally accepted practice and/or guidelines from a nationally recognized entity for the diagnosis being treated have been exhausted.

Limitations

The duration of coverage will be limited to three (3) months UNLESS:

a. If the FDA-approved package insert limits the recommended duration of therapy for the requested diagnosis to be less than 3 months, duration of coverage will be limited to the recommended duration of therapy specified in the FDA-approved package insert, OR
b. If requesting duration of coverage that is more than the recommended duration of therapy specified in the FDA-approved package insert, duration of coverage can exceed the recommended duration of therapy up to a maximum of 3 months as deemed medically necessary by the plan.

References
N/A

Review History
06/25/2018 – Reviewed
10/01/2018 – Implemented
01/22/2019 – Reviewed P&T
01/22/2020 – Reviewed at P&T
01/20/2021 – Reviewed and updated for Jan P&T; updated Limitations to include "complete course of therapy if therapy is less than 6 months". Effective 03/01/21.
09/21/2022 – Reviewed at Sept P&T; Separated Comm/Exch vs MH policy; no clinical updates.
04/12/23 – Reviewed for P&T. Updated approval durations to 3 months. Verbiage updates. Effective 4/1/23.