

**New to Market**  
**Effective 03/01/2021**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

### 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 6 months or up to a complete course of therapy if therapy if less than 6 months as per noted in the FDA approved package insert or 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.

