

Pharmacy Policy Bulletin: J-0767 New to Market Drug Policy- Commercial and Healthcare Reform	
Number: J-0767	Category: Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	Benefit(s): Commercial (1., 2., 3., 4., 5., 6., 7., or 8.): 1. Miscellaneous Specialty Drugs Oral = Yes w/ Prior Authorization 2. Miscellaneous Specialty Drugs Injectable = Yes w/ Prior Authorization 3. Other Managed Prior Authorization = Yes w/ Prior Authorization 4. Rx Mgmt Performance = Deterrent/Patent Extenders 5. Rx Mgmt Performance = Deterrent/Patent Extenders + Guideline 6. Rx Mgmt Performance = MRXC = Yes 7. Rx Mgmt Step Therapy = Preferred 8. Rx Mgmt Step Therapy = Minimal Step Therapy = Yes Healthcare Reform: Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	Additional Restriction(s): May not apply to <i>select</i> Commercial and/or HCR formularies
Version: J-0767-010	Original Date: 03/04/2015
Effective Date: 07/18/2025	Review Date: 06/25/2025

Drugs Product(s):	• Select New to Market Drugs
FDA-Approved Indication(s):	• See individual product information

Background:	This policy defines the criteria under which coverage for a new to market drug will be considered under the prior authorization request process. This policy is superseded if the medication for request is included in a separate policy, including the Market Watch New to Market Program, if applicable, based on the member's benefit. The Pharmacy & Therapeutics (P&T) Committee reviews current literature to determine the benefits and risks of new medications within the Plan's population. The criteria below may be used to evaluate individual requests for coverage of a new to market medication or new indication(s) for currently available medications that are awaiting
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review by the Plan's P&T Committee and/or implementation of a P&T Committee approved policy.

Approval Criteria

I. Approval Criteria

When a benefit, coverage of a new to market product may be approved when all of the following criteria are met **(A., B., and C.)**:

- A. The medication must be used for an FDA approved indication.
- B. If the medication is an authorized generic, the member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(1. and 2.)**:
 - 1. The respective brand product
 - 2. All other plan-preferred products in the medication's therapeutic category
- C. If the request is for a new to market oral liquid dosage form (for example, oral solution/suspension) of a chemical entity that is commercially available as a solid oral dosage form (for example, tablets/capsules), the member has met the criteria outlined in policy J-1283.

- II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.
- III. Coverage of oncology medications listed in this policy may be approved on a case-by-case basis per indications supported in the most current NCCN guidelines.

Limitations of Coverage

- I. Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Automatic Approval Criteria

None

For previous versions, please see policy [J-0419](#).

Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.