



MASSACHUSETTS

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Pharmacy Medical Policy New Drug Approval Program

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Policy Number: 005

BCBSA Reference Number: None

Related Policies

- [#251](#) Drug Management and Prior Authorization
- [#434](#) Formulary Exception Form

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider website or directly on the web at <https://provider.express-path.com>. Patients must have pharmacy benefits under their subscriber certificates.

New Drug Approval Process

For most BCBSMA products, we have an evaluation period before adding new, FDA-approved brand-name drugs to our formulary. During this period, the drug will be considered non-formulary/non-covered, and clinical and/or administrative requirements/policy may be required while our Pharmacy and Therapeutics Committee analyzes current literature to determine, among other things, the benefits and risks of each new drug under review. While we may ~~will~~ automatically impose this evaluation period for all brand-name drugs after they receive FDA approval, we may ~~will~~ not do so for most generic drugs. See policy 251 for non-formulary clinical criteria requirement.

Once our Pharmacy and Therapeutics Committee has completed their review and we have decided whether a drug will be included on or excluded from the BCBSMA covered drug list, we will update our formulary. During the time when the drug is being evaluated, physicians can request an exception in the case of medical necessity. New to market medications will continue to be considered non-covered until the evaluation process is completed. Physicians may request a medical necessity exception while these products are being evaluated and approval for these requests will be based on the FDA approved

indications for the new to market medication and if the new drug being evaluated belongs to a therapeutic class that BCBSMA manages through prior authorization, formulary Step Therapy or Quality Care Dosing, the established current criteria will be applied to the request. For exception requests for a new to market medication for a non-FDA approved indication, individual consideration will be applied and providers should submit supporting clinical documentation for review.

Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts
Clinical Pharmacy Department
One Enterprise Drive
Quincy, MA 02171
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Managed Care Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale. Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

PPO and Indemnity Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients who do not meet the step-therapy criteria at the point of sale. Pharmacy Operations: (800) 366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria at the point of sale.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAtH which can be found on the BCBSMA provider portal or directly on the web at <https://provider.express-path.com>.

Policy History

Date	Action
8/2014	Updated language and format.
2/2014	Update Operations contact info
5/2011	Update, criteria for approval of new to market medications while under review; remove drug table
4/1/2000	New policy, effective 4/1/2000

Request for Outpatient Retail Pharmacy Prior Authorization

Fax to: Clinical Pharmacy Program (800) 583-6289

Phone Authorization (800)366-7778 or Web: <https://provider.express-path.com>

To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

We cannot process requests unless they contain all of the information requested below:	
Patient Information (REQUIRED)	
Name	
BCBSMA ID Number	
Is the patient a BCBSMA employee? If yes, please fax request to: (617) 246-4013	Yes No
Date of Birth	
Patient's Diagnosis	
Physician Information (REQUIRED)	
Name	
Medical Specialty	
BCBSMA Provider number/NPI number	
Telephone Number	
Fax Number	
Is this fax number 'secure' for PHI receipt/transmission per HIPAA requirements? (circle one)	Yes No
Contact Name (if different from physician)	
Please select one of the three following sections to complete, depending on the nature of your request for the above-named patient.	
Formulary Exception Request	
Name of non-covered drug you want to prescribe	
Reason for Individual Consideration Request (please check one):	
<input type="checkbox"/> Treatment failure with the following covered drugs in class:	
<input type="checkbox"/> Documented adverse reaction to the following covered drugs:	
<input type="checkbox"/> Other clinical reason (please specify) _____	
Quality Care Dosing Override Request	
Drug name, strength and quantity requested:	
Clinical reason for override (please specify)	
Outpatient Retail Pharmacy Prior Authorization Request	
Drug name:	
Start/End date (must be one year or less):	
Associated Co-morbid diagnosis:	
MD Signature:	Date: