



MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy New Drug Approval Program

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Policy Number: 005

BCBSA Reference Number: None

Related Policies

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

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. 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 automatically impose this evaluation period for all brand-name drugs after they receive FDA approval, we may 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.

New Indication Process

When a new indication is approved by the FDA for an existing medication and a policy exists for that

medication – This policy will hold that medication under review until either a Pharmacy & Therapeutics review is completed or a business review is completed. If an existing medication without a policy is approved with a new FDA indication -- This policy may hold that medication under review until either a Pharmacy & Therapeutics review is completed or a business review is completed. In either instance of a new FDA indication the medication will be considered both non-formulary and not covered while under 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
 Pharmacy Operations Department
 25 Technology Place
 Hingham, MA 02043
 Tel: 1-800-366-7778
 Fax: 1-800-583-6289

Prior Authorization Information

Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is required .
Commercial PPO and Indemnity	Prior authorization is required .

Policy History

Date	Action
6/2017	Updated address for Pharmacy Operations.
11/2016	Updated to add New Indication language.
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

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<http://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>