



MASSACHUSETTS

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

## Pharmacy Medical Policy

### Drug Management & Prior Authorization

#### Table of Contents

- [Policy: Commercial](#)
- [Information Pertaining to All Policies](#)
- [Endnotes](#)
- [Policy: Medicare](#)
- [References](#)
- [Forms](#)
- [Policy History](#)

#### Policy Number: 251

BCBSA Reference Number: None

#### 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.

#### Our Formulary

BCBSMA maintains a formulary, or a list of covered drugs. At this time, the BCBSMA formulary applies to most members of group HMO, PPO, POS, and indemnity products, and some members of Managed Blue for Seniors. It also applies to members of the direct-pay products HMO Blue-Direct and PPO Blue-Direct. At this time, the formulary does not apply to Medicare Advantage, Medex<sup>®</sup>, direct-pay products such as Managed Major Medical, Comprehensive Managed Major Medical and certain Managed Blue for Seniors plans.

#### Which Drugs are Included?

You can obtain a complete list of BCBSMA non-covered drugs on the BCBSMA.com website under Medical Policies #[433](#).

#### If a patient has a Medical Basis for a Non-Covered Drug

In order to promote clinically appropriate and cost-effective prescription drug use, BCBSMA may require the use of a BCBSMA formulary drug prior to allowing benefit coverage for a non-formulary drug. Pharmacy benefits and coverage are generally not provided for non-formulary drugs because safe and effective prescription alternatives generally are available on the BCBSMA formulary. The BCBSMA formulary drugs, the covered alternatives in this policy, are used and accepted by regulatory, medical and

pharmacy communities. If allowed with Formulary Exception request, the non-formulary drug coverage will be at the highest copayment level and terms as the Plan allows

### **Clinical Coverage Criteria:**

BCBSMA may authorize coverage for non-formulary prescription medications for a member who meets one of the following clinical criteria:

- The member has documented treatment failure with two covered formulary drugs (NOTE: If only one covered formulary drug is available, the member must have documented treatment failure with that alternative); **or**
- The member has documented adverse effects to two covered formulary drugs, significant enough to preclude use of the covered formulary drug (NOTE: If only one covered formulary drug is available, the member must have documented treatment failure with that alternative); **or**
- There is some other specified clinical basis

You can request continued coverage of a non-covered drug through our clinical exception program for members when there is a medical basis for the member not being able to take any of the covered drugs from the same therapeutic class. Physicians or their representatives may call BCBSMA Pharmacy Operations department to request a review for formulary exception for their patients at (800)366-7778. Physicians may also submit requests for retail pharmacy exceptions via the web using Express P<sub>A</sub>th which can be found on the BCBSMA provider website or directly on the web at <https://provider.express-path.com>

Physicians may also request an exception review in writing by using the Formulary *Exception Form*. The Formulary Exception form is included as part of this document for physicians to submit for patients.

Fax or mail the completed form to BCBSMA. We will respond to your request within two business days of receipt.

### **New Drug Approval Process**

For all 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 (please see the above section titled Our Formulary) while our Pharmacy and Therapeutics Committee analyzes current literature to determine, among other things, the benefits and risks of each new brand-name drug. While we will automatically impose this evaluation period for all brand-name drugs after they receive FDA approval, we will not do so for generic drugs.

Once 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. If the new drug being evaluated belongs to a therapeutic class that BCBSMA manages through prior authorization, step therapy, formulary or Quality Care Dosing, the established current criteria will be applied to the request. Follow the directions above to obtain the *Formulary Exception Form*.

### **Drug Coverage Benefits**

- RU486 (mifepristone):<sup>14, 16</sup> Covered only for those plans with voluntary termination of pregnancy benefits.
- For a list of drugs requiring prior authorization, see below.
- For Quality Care Dosing guidelines, see 621.
- Birth control pills (oral contraceptive pills), birth control (contraceptive) transdermal patches and birth control (contraceptive) vaginal rings are covered according the patient's subscriber certificate.
- Off-label use of drugs for cancer or HIV/AIDS are covered according to the Massachusetts state mandate. Some self-insured accounts may not provide coverage for drugs listed in the

Massachusetts state mandate. Such drugs must be recognized for the treatment of HIV or the specific cancer, and published in scientific literature such as one of the following references:

United States Pharmacopeia Drug Information

American Medical Association Drug Evaluation

American Hospital Formulary Service Drug Information

- Enteral formula is covered according to the Massachusetts state mandate and BCBSMA's Medical Policy coverage criteria. Some self-insured accounts may not provide coverage for enteral formula as listed in the Massachusetts state mandate.

### Off-Label Indications

The Food and Drug Administration (FDA) requires that a drug be subject to clinical studies and be FDA approved prior to, and for, prescription use so that the drug's efficacy and safety is proven.<sup>17</sup> A product approved in this manner for marketing is commonly termed an "FDA-approved drug." A drug product sponsor must submit to and have approved by the FDA, the product's NDA, ANDA, or BLA (New Drug Application, Abbreviated New Drug Application, or Biologic License Application). The FDA approves a drug product and, among other things, its labeling (container label, package insert, and prescribing information leaflet), dosing and uses.<sup>18</sup>

The Food, Drug and Cosmetic Act (FDCA) does not limit the manner in which a physician may use an approved drug. Once a product has been approved for prescription, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in the FDA approved labeling. Such "unapproved" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.<sup>19</sup> These unapproved uses are frequently called "off-label" uses. While it allows individual personal professional innovation, off-label prescription may discourage, and is not, evidence based practice.

While the FDA provides indication-specific use for drugs, the FDA focus is on market entry for prescription drugs rather than regulating physicians' prescribing practices. A prescriber's prescription of a drug for uses beyond those formally evaluated by the manufacturer's studies and approved by the FDA is not regulated by the FDA. Off-label prescribing of medications is often thought to be supported by scientific evidence. However, it very often is not and off-label prescription raises key concerns about patient efficacy and safety risks, and costs to the health care system.<sup>17</sup>

Although most prescriptions in a recent study (575 million [79%]) were for FDA approved indications, many (150 million [21%]) lacked FDA approval for the condition they were used to treat.<sup>17</sup> "The greatest disparity between supported and unsupported off-label prescription occurred among psychiatric (4% strong support vs. 96% limited or no support) and allergy therapies (11% strong support vs. 89% limited or no support)."<sup>17</sup>

While allowed to do so, drug prescription for an indication or use not FDA approved requires the prescriber to be "well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner *when the intent is the "practice of medicine"* does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB)."<sup>20</sup>

Many off-label uses are effective, well documented in peer-reviewed literature, and commonly used when drugs with labeled uses fail. Criteria in drugs-specific policies take precedence over the criteria used in this policy. Therefore, drug-specific policies must be reviewed prior to applying the criteria listed below. However, this policy should be applied when drug-specific policy is silent for an off-label use of a FDA approved drug or when developing drug-specific medical policies. Also, Commercial contracts governed by the Commonwealth of Massachusetts insurance law may be subject to the mandates and or Compendia applicability under state and or federal law or regulation.

Off-label, or unlabeled, uses of prescription drugs may be considered medically necessary for use when positive health outcomes result, as evaluated by one or all of the following criteria:

- Well-designed and well-conducted investigations published in peer-review journals;
- Published in recognized and widely subscribed clinical journals such as, but not limited to, Journal of American Medical Association, New England Journal of Medicine, and Lancet;
- Evidence that demonstrates clinical improvement and can be measured;
- Beneficial effects should outweigh any harmful effects;
- Beneficial effects must exceed the net health outcome of established alternatives;
- Opinions and evaluations by national or other professionally recognized medical associations that support the scientific quality and use of the supporting evidence and rationale;
- Must be in the usual conditions of medical practice and not an investigational setting or conditions<sup>21</sup> and or
- Inclusion in one or more CMS recognized compendia.<sup>22,23</sup>

The Department of Health and Human Services (DHHS), Centers for Medicare & Medicaid Services (CMS), has published and implemented a process for drugs prescribed for off-label use only if the drugs are identified as safe and effective for that use in one of three officially recognized drug compendia. The three compendia identified in the Medicare statute are:

- (1) the American Hospital Formulary Service – Drug Information (AHFS-DI)
- (2) the United States Pharmacopeia – National Formulary (or its successor publication)
- (3) DRUGDEX Information System.

Only one compendium need approve an off-label usage for Medicare Part D to cover it.<sup>22</sup>

Additionally, DHHS CMS has published that for use in the determination of a “medically-accepted indication” of drugs and biologicals used off-label in an anti-cancer chemotherapeutic regimen, the following are accepted:

- (1) American Hospital Formulary Service-Drug Information (AHFS-DI)
- (2) NCCN Drugs and Biologics Compendium
- (3) Thomson Micromedex DrugDex
- (4) Clinical Pharmacology.<sup>22</sup>

Generally and while the different compendia use different criteria, a use is identified by a compendium as medically accepted if the: indication is a Category 1 or 2A in NCCN, or Class I, Class IIa, or Class IIb in DrugDex; or, (2) narrative text in AHFS or Clinical Pharmacology is supportive. A use is not medically accepted by a compendium if the: (1) indication is a Category 3 in NCCN or a Class III in DrugDex; or, (2) narrative text in AHFS or Clinical Pharmacology is “not supportive.” The complete absence of narrative text on a use is considered neither supportive nor non-supportive.<sup>23</sup>

## Drug Coverage Exclusions

We do not cover the following:

- Products that are not FDA-approved or that have no FDA-approved indications
- Products that are available over-the-counter, unless specified in the subscriber certificate
- Procuren<sup>TM</sup>, a growth factor for wound-healing, because it has not been conclusively proven to improve wound healing.<sup>1</sup> See also policy #435, wound healing.
- Cosmetic drugs, including the following:
  - Products used to stimulate hair growth
  - Depigmenting agents to lighten skin color
  - Retinoic acid derivatives other than listed under “Prior Authorization”
  - Botulinum toxin when used for cosmetic purposes.

- Prescription multi-vitamins; however, most plans cover prenatal and pediatric multivitamins
- Anorexiants for weight loss. Several of these prescription drugs (Redux<sup>®</sup>, Pondimin<sup>®</sup>, which is part of the “Phen-Fen” combination) were removed from the market by their manufacturers after the FDA presented information to the manufacturers regarding numerous cases of heart damage in patients who were taking these drugs.

### What is Prior Authorization?

For certain FDA-approved drugs that are included on BCBSMA’s covered drug list, we require the physician to obtain prior authorization before we reimburse the cost of the prescription drug. This is generally required in cases where the patient must meet certain medical necessity criteria. Patients must have pharmacy benefits under their subscriber certificates to be covered for the drugs that require prior authorization.

### List of Drugs Requiring Prior Authorization

The following list details drugs that require prior authorization. In certain cases noted, we require prior authorization only for Medex, Managed Blue for Seniors, **Medicare HMO Blue and Medicare PPO Blue members**, in order to coordinate benefits with Medicare.

Where an individual Medical Policy exists for the listed drug, the document number is listed in the middle column. The generic name of each drug is listed first. If applicable, the trade name is listed in parentheses.

Drugs that require prior authorization:	Document:	Coverage Note:
Alglucerase (Imiglucerase <sup>®</sup> )	<a href="#">317</a>	Prior authorization required for all plans.
Alpha-1 antitrypsin (Prolastin <sup>®</sup> )	<a href="#">279</a>	Prior authorization required for all plans. As of October 1, 1999 patients must be enrolled with the Bayer Direct National Registry.
Amphetamines, CNS stimulants and psychotherapeutic agents	<a href="#">019</a>	Prior authorization required for all plans, only for patients over age 17. No prior authorization required for members under age 17. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits may apply. See Medical Policy 019 for details.
Ampyra <sup>™</sup> (dalfampridine)	<a href="#">246</a>	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 246 for details.
Angiotensin II Receptor Antagonists	<a href="#">012</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 012 for details.
Anti-depressants	<a href="#">024</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 024 for details.
Antifungal Therapy for onychomycosis	251	For the following generic antifungal agents (ciclopirox, itraconazole and terbinafine) no prior authorization will be required for initial treatment: itraconazole and terbinafine 12 weeks of therapy; ciclopirox nail lacquer 48 weeks of therapy. For treatment past the initial treatment course, prescribers may request an individual consideration exception request and provide additional supporting

Drugs that require prior authorization:	Document:	Coverage Note:
		documentation for continued treatment. The brand name medications (CNL8 nail kit, Lamisil granules, Lamisil tablets, Onmel tablets, Penlac nail lacquer, Sporanox capsules and Terbinex tablets) are non-covered medications on the BCBSMA formulary. If the member requires treatment with one of these medications, the member must have treatment failure with or a contraindication to two of the covered generic products. If the formulary exception is granted, the authorization will be for the initial length of therapy as indicated for the generic products above. For treatment past the initial course, prescribers may request an individual consideration exception request and provide additional supporting documentation for continued treatment.
Antihyperlipidemics	<a href="#">013</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 013 for details.
Asthma and Chronic Obstructive Pulmonary Disease Medication Management (Leukotrienes and Inhaled Combination Products)	<a href="#">011</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits may apply See Medical Policy 011 for details.
Atypical Antipsychotics	<a href="#">458</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 458 for details.
B-Type Natriuretic Peptide	<a href="#">031</a>	Prior authorization required for all plans. See Medical Policy 031 for details.
Benign Prostatic Hypertrophy (BPH)	<a href="#">040</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 040 for details.
Bisphosphonate, Infusion/Injection	<a href="#">061</a>	Prior authorization is required for all outpatient sites of service. See Medical Policy 061 for details.
Bisphosphonate, Oral	<a href="#">058</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 058 for details.
Botulinum toxin	<a href="#">006</a>	Prior authorization is required for all outpatient sites of service. See Medical Policy 006 for details.
Botulinum Toxin for the Treatment of Hyperhidrosis	<a href="#">405</a>	Prior authorization required for all plans. See Medical Policy 405 for details.
BRAF Kinase and MEK inhibitors for Unresectable or	<a href="#">409</a>	Prior authorization required for all plans. See Medical Policy 409 for details.

Drugs that require prior authorization:	Document:	Coverage Note:
Metastatic Melanoma		
Cinryze™ (C1 Inhibitor (Human))	<a href="#">112</a>	Prior authorization is required for all outpatient sites of service. Covered only under the medical benefit. See Medical Policy 112 for details.
Compounded Medications	<a href="#">579</a>	Prior authorization required for all plans. See Medical Policy 579 for details.
COX II Inhibitor Drugs	<a href="#">002</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 002 for details.
Cox II Inhibitor Drugs Authorization Form	<a href="#">432</a>	Cox II Inhibitor Drugs Authorization Form.
Crizotinib (Xalkori®)	<a href="#">410</a>	Prior authorization required for all plans. See Medical Policy 410 for details.
Cyclophosphamide (Cytoxan®)	251	Prior authorization required only for Medicare HMO Blue and Medicare PPO Blue, Managed Blue for Seniors and Medex members. May be covered by Medicare.
Cyclosporine ophthalmic solution (Restasis®)	<a href="#">426</a>	Prior authorization required for all plans. See Medical Policy 426 for details.
Diabetes Step Therapy – Second Step Agents	<a href="#">041</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 041 for details.
Dopamine Agonists, non-ergot derived	<a href="#">119</a>	Prior authorization required for Standard plans. Step Therapy edits apply at Point-of-Sale. See Medical Policy 119 for details.
Epidermal Growth Factor Receptor (EGFR) Inhibitors	<a href="#">114</a>	Prior authorization is required for all outpatient sites of service. Covered only under the medical benefit. See Medical Policy 114 for details.
Erythropoietin, Recombinant Human (Epogen®, Procrit® or Aranesp®)	<a href="#">262</a>	Prior authorization required for all plans. May be covered by Medicare. Quality Care Dosing limits apply. See Medical Policy 262 for details.
Erectile dysfunction drugs	<a href="#">078</a>	Prior authorization adjudicated at the point of sale. Supply limited to 4 units per 30-day period for all erectile dysfunction drugs.
Factor VIII and IX	<a href="#">360</a>	Prior authorization required for all plans. Covered only as a home infusion therapy benefit. See Medical Policy #360 for details.
Fentanyl, oral/transmucosal	<a href="#">113</a>	Prior authorization required for Standard plans. Quality Care Dosing limits apply. See Medical Policy 113 for details.
Formulary Exception or Outpatient Retail Pharmacy Prior	<a href="#">434</a>	Formulary Exception or Outpatient Retail Pharmacy Prior Authorization.

<b>Drugs that require prior authorization:</b>	<b>Document:</b>	<b>Coverage Note:</b>
Authorization		
Glucagon-like Peptide-1 (GLP-1) Receptor Agonists	<a href="#">282</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 282 for details.
Granulocyte & Granulocyte-Macrophage Colony Stimulating Factors (G-CSF and GM-CSF)	<a href="#">337</a>	Prior authorization required for all plans. See Medical Policy 337 for details.
Growth hormone	<a href="#">257</a>	Prior authorization required for all plans. See Medical Policy 257 for details.
Hepatitis C Medications	<a href="#">344</a>	Prior authorization required for all plans. See Medical Policy 344 for details.
Home infusion therapy	<a href="#">430</a>	Prior authorization required for all plans. Note: Per diem not covered by Medex.
Hydroxyprogesterone caproate (Makena™)	<a href="#">314</a>	Prior authorization required for all plans. See Medical Policy 314 for details.
Hypnotics	<a href="#">033</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 033 for details.
IgE Receptor Binding Inhibitors (Xolair®)	<a href="#">017</a>	Prior authorization required for all plans. Covered only as a home infusion therapy benefit.
Immune Modulating Drugs	<a href="#">004</a>	Prior authorization required for all plans. Step therapy edits apply. Quality Care Dosing limits apply. See Medical Policy 004 for details.
Immunomodulators, topical	<a href="#">010</a>	Prior authorization required for all plans. See Medical Policy 010 for details.
Infertility drugs	251	Covered only when a member has received prior authorization for infertility treatment.
Influenza Drugs	<a href="#">440</a>	Covered at highest tier for a limited quantity.
Injectable Clostridial Collagenase for Fibroproliferative Disorders	<a href="#">225</a>	Prior authorization required for all plans. Covered only as a medical or home infusion therapy benefit. See Medical Policy 225 for details.
Injections for osteoarthritis	<a href="#">427</a>	Prior authorization required for all plans. See Medical Policy 427 for details.
Interferons ( $\alpha, \gamma$ )	<a href="#">052</a>	Prior authorization required for all plans. See Medical Policy 052 for details.
Interleukin-2 (IL-2)	<a href="#">103</a>	Prior authorization is required when these medications are processed under the home infusion therapy or retail pharmacy

Drugs that require prior authorization:	Document:	Coverage Note:
		benefit. Prior authorization is not required when these medications are purchased by the physician and administered in the office in accordance with medical policy guidelines. See Medical Policy 103 for details.
Intravitreal Angiogenesis Inhibitors for Choroidal Vascular Conditions	<a href="#">343</a>	Prior authorization required for all plans. Covered only as a medical or home infusion therapy benefit. See Medical Policy 225 for details.
IVIg Immunoglobulin	<a href="#">310</a>	Prior authorization required for all plans. Covered only as a home infusion therapy benefit. Note: Per diem not covered by Medex.
Ivacaftor (Kalydeco™)	<a href="#">408</a>	Prior authorization required for all plans. See Medical Policy 408 for details.
Lorcaserin (Belviq®)	<a href="#">572</a>	Prior authorization required for all plans. See Medical Policy 572 for details.
Medicare Part D Coverage Determination Request Form	<a href="#">442</a>	Medicare Part D Coverage Determination Request Form
Morphine: preservative-free solution	251	Prior authorization required for all plans. Covered only as a home infusion therapy benefit. Note: Per diem not covered by Medex.
Natalizumab (Tysabri®)	<a href="#">062</a>	Prior authorization required for all plans. See Medical Policy 062 for details.
New Drug Approval Program	<a href="#">005</a>	Applies to all plans. See Medical Policy 005 for details.
Non-covered Drug List	<a href="#">433</a>	Applies to all plans with a closed formulary.
Ophthalmic Prostaglandin	<a href="#">346</a>	Prior authorization required for all plans. Step therapy edits apply. See Medical Policy 346 for details.
Opioid Medication Management	<a href="#">102</a>	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 102 for details.
Organ transplant rejection drugs: Azathioprine (imuran®), Mycophenolate (Cellcept®) Cyclosporine (Sandimmune® or Neoral®) Tacrolimus	251	Prior authorization required only for Medex, Managed Blue for Seniors, Medicare HMO Blue and Medicare PPO Blue members. Covered for transplants only when Medicare has approved the transplant. Effective 12/21/00, lifetime coverage is provided for self-administered immunosuppressive drug therapy following a Medicare covered transplant. 11,15

Drugs that require prior authorization:	Document:	Coverage Note:
(Prograf®) Daclizumab (Zenapax®) Basiliximab (Simulect®) Muronmonab-CD3 (Orthoclone OKT3)		
Outpatient Medical Prior Authorization Form	<a href="#">166</a>	Outpatient Medical Prior Authorization Form
Overactive Bladder Medications	<a href="#">170</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 170 for details.
Phosphodiesterase Type-5 Inhibitors for Pulmonary Arterial Hypertension	<a href="#">036</a>	Prior authorization required for all plans. See Medical Policy 036 for details.
Pregabalin (Lyrica®)	<a href="#">057</a>	Prior authorization required for all plans. See Medical Policy 057 for details.
Progesterone Therapy as a Technique to Reduce Preterm Birth in High-Risk Pregnancies	<a href="#">552</a>	Prior authorization required for all plans. See Medical Policy 552 for details.
Proton Pump Inhibitors	<a href="#">030</a>	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 030 for details.
Quality Care Dosing (QCD) Guidelines	<a href="#">621</a>	Quality Care Dosing (QCD) Guidelines.
Recombinant and Autologous Platelet-Derived Growth Factor as a Treatment for Wound Healing and Other Conditions	<a href="#">186</a>	Prior authorization is required for all outpatient sites of service. See Medical Policy 186 for details.
Repository Corticotropin Injection (H.P. Acthar® Gel)	<a href="#">294</a>	Prior authorization required for all plans. See Medical Policy 294 for details.
Retinoic acid	251	Prior authorization required only for patients over age 30.

Drugs that require prior authorization:	Document:	Coverage Note:
derivatives		Coverage for all ages is restricted to non-cosmetic purposes only. Under the state mandate for cancer drugs, FDA-approved retinoids are covered for some active cancers, such as actinic keratosis.
RSV-Immunoprophylaxis	<a href="#">422</a>	Prior authorization required for all plans.
Special medical formulae/enteral feedings	<a href="#">304</a>	Prior authorization required for all plans. No prior authorization required for members under age one. See Medical Policy 304 for details.
Suboxone® and Buprenorphine Containing Products	<a href="#">094</a>	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 094 for details.
Tamiflu® & Relenza® Form for Physicians and Members	<a href="#">441</a>	Tamiflu® & Relenza® Form for Physicians and Members.
Teriparatide (Forteo®)	<a href="#">018</a>	Prior authorization required for all plans. See Medical Policy 018 for details.
Topical Testosterones	<a href="#">345</a>	Prior authorization required for all plans. Step therapy edits apply. See Medical Policy 345 for details.
Total Parenteral Nutrition (TPN)	<a href="#">296</a>	Prior authorization required for all plans. Covered only as a home infusion therapy benefit. Note: Per diem not covered by Medex.
Zytiga® (abiraterone)– Xtandi® (enzalutamide) for Prostate Cancer	<a href="#">571</a>	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 571 for details.

### 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  
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.  
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.
- 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>.

### PPO and Indemnity Authorization Instructions

- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.  
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.
- 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>.

### Policy History

Date	Action
2/2014	Updated list of pharmacy policies, to remove retired and add new policies and add hyperlinks to the policy numbers.
1/2013	Updated 1/2013 to update index with new and retired policies and to include coverage policy for off-label indications.
7/2012	Updated to include new Pharmacy Medical Policies: Opioid Medication Management #102 and Suboxone <sup>®</sup> and Buprenorphine Containing Products #094. Also updated to include dispensing limits within policy #251, add information to policy #168 and #119 coverage notes and add medical policies Angiotensin II Receptor Antagonists #012 and Hypnotics #033.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.

### References

1. Revised 1/96 based on a TEC (Technology Evaluation Center) 1992 assessment of growth factors for wound healing, including bFGF, EGF, PDAF, PDGF, PF-4, TGF- $\alpha$ , TGF- $\beta$ . Medical literature was analyzed from 1983-1992. 8 articles on platelet-derived wound healing formula (PDWHF) were evaluated. The 2 randomized trials on autologous PDWHF reported conflicting results. Krupski (1991) found no beneficial effect over placebo, while Knighton found significantly better healing. It is unclear whether the inconsistencies of these results were related to potency differences (as measured by beta-thromboglobulin levels). Steed (1991) described 2 randomized controlled trials, the first did not report a statistical conclusion, but there appeared to be no difference from placebo. The second study (higher doses) reported evaluable data on only 13 of 36 patients. Other studies were not designed as randomized blinded placebo-controlled trials. There was little data available on other growth factors. DATTA (Diagnostic and Therapeutic Technology Assessment) 1995: the role of platelets in wound healing has been suggested, but without sufficient published data it is not possible to determine clinical effectiveness or whether its use may be appropriate and acceptable. Besides 2 uncontrolled studies, (Knighton, Annals of Surgery 1986; 204:322-330 and Atri, Surgery 1990;108:508-512) there has been only 1 controlled study by Knighton, Surg Gynecol Obstet 1990;170:56-60; the study sample was small and randomization was not stratified according to diagnostic groups. NIH concurred with DATTA's report and indicated that there was insufficient data

to establish the benefit of platelet extract upon wound healing. Although the limited information may suggest a salutary effect, further studies are needed.

2. See FDA labeling
3. Revised 3/96 to include further information on controlled substances. There is insufficient scientific evidence to support the use of amphetamines to treat depression.
4. Revised 5/1/96. Effective 5/1/96.
5. Amphetamine drugs include: Amphetamine, Dexedrine, Ferndex, Oxydess, Spacap, Dexosyn, Adderal, and Methamphetamine.
6. See the NIH's Agency for Health Care Policy and Research's Clinical Practice Guideline on Management of Cancer Pain, No. 9 March 1994. AHCPH Publication No. 94-0592 pages 58-59.
7. Revised 4/97 to include Ritalin as an amphetamine-like substance.
8. Revised 4/97 to include infertility drugs.
9. Revised 11/97 to add the list of drugs that require prior authorization for Medicare HMO Blue and Medicare PPO Blue and Medex, in accordance with Medicare.
10. Revised 9/98 to include off-label indication for Retin A.
11. In accordance with Medicare Managed Care Organization Regional Bulletin, #2000-02; issued 1/13/2000.
12. Revised 1/99 based on the 11/99 decision of the BCBSMA Pharmacy and Therapeutics Committee of practicing doctors from across Massachusetts.
13. Based on recommendations from the Clinical Pharmacy Unit, May 2000.
14. Based on recommendations from the Pharmacy and Therapeutics Committee 9/11/07.

If an extension for Orlistat™ were denied due to the lack of required weight loss, members would need to provide proof of commitment to lose weight before an extension is considered. Proof of commitment to lose weight include:

- *Pay cash for 30-day supply and provide documented weight loss*
  - *Provide letter of commitment plan and goals signed by MD and member*
  - *Proof of regular attendance/participation in an exercise program*
  - *Proof of regular attendance/participation in Weight Watchers®*
  - *Proof of regular attendance/participation in Natural Healthy Rewards Program.*
14. FDA guidelines require that the drug must only be dispensed by the physician providing the overall management of the medical termination of pregnancy. Physician privileging will be managed by the FDA. Specific physician qualifications include:
- Ability to assess duration of pregnancy accurately
  - Ability to diagnose ectopic pregnancies
  - Ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or have made plans to provide such care through other qualified physicians, and are able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary
  - Has read and understood the prescribing information on Mifeprex
  - Must provide each patient with a Medication Guide and must fully explain the procedure to the patient, provide her with a copy of the guide and Patient Agreement, give her an opportunity to read and discuss both the medication guide and the Patient Agreement
  - Obtain her signature on the Patient Agreement and must sign this as well
  - Must notify the sponsor or its designate in writing under the heading "Dosage and Administration" in the event of an ongoing pregnancy which is not terminated subsequent to the conclusion of the treatment procedure
  - Must report any hospitalization, transfusion, or other serious events to the sponsor
  - Must record the drug name, package serial # in each patient's record.
15. In accordance with the 1/24/01 Centers for Medicare and Medicaid Services (CMS) Program Memorandum, Transmittal AB-01-10. See also: <http://www.hcfa.gov/pubforms/transmit/AB0110.pdf>
16. RU486 (mifepristone) is FDA-approved for termination of intrauterine pregnancy: For medical termination of intrauterine pregnancy through 49 days of pregnancy. For purposes of this treatment, pregnancy is dated from the first day of the last menstrual period in a presumed 28-day cycle with ovulation occurring at mid-cycle. Duration of pregnancy is determined from menstrual history and by

clinical examination. If the duration of pregnancy is uncertain, or ectopic pregnancy is suspected, ultrasound scan should be done. Patients taking mifepristone must take 400 mcg of misoprostol 2 days after taking mifepristone unless a complete abortion has already been confirmed before that time. Pregnancy termination by surgery is recommended in cases when mifepristone and misoprostol fail to cause termination of intrauterine pregnancy.

Unlabeled uses include: Postcoital contraception/contragestation, intrauterine fetal death/nonviable early pregnancy, unresectable meningioma, endometriosis and Cushing's syndrome.

<sup>17</sup> Arch Intern Med. 2006;166:1021-1026

<sup>18</sup> American Society of Hospital Pharmacists. ASHP statement on the use of medications for unlabeled uses. *Am J Hosp Pharm.* 1992; 49:2006–8.

<sup>19</sup> Use of approved drugs for unlabeled indications. FDA Drug Bull. 1982; 12:4–5.

<sup>20</sup> United States Food and Drug Regulation. Regulatory Information. "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet. Guidance for Institutional Review Boards and Clinical Investigators.

<sup>21</sup> Drugs, unlabeled use Off-label drug use. BCBSA Policy 5.01.01. Archived 12/08/11.

<sup>22</sup> Center for Medicare Advocacy. CMA Report: Medicare Coverage for Off-Label Drug Use. September 7, 2012

<sup>23</sup> Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologics Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen, Pub. 100-02 Medicare Benefit Policy, chapter 15, section 50.4.5.

**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>**

We plan to respond to your request within two business days of our receipt. 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 <b>all</b> of the information requested below:	
<b>Patient Information (REQUIRED)</b>	
Name	
BCBSMA ID Number	
Is the patient a BCBSMA employee? If yes, please fax request to: <b>(617) 246-4013</b>	Yes                      No
Date of Birth	
Patient's Diagnosis or ICD-9-CM code	
<b>Physician Information (REQUIRED)</b>	
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 <b>one</b> of the three following sections to complete, depending on the nature of your request for the above-named patient.	
<b>Formulary Exception Request</b>	
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) _____	
<b>Quality Care Dosing Override Request</b>	
Drug name, strength and quantity requested:	
Clinical reason for override (please specify)	
<b>Outpatient Retail Pharmacy Prior Authorization Request</b>	
Drug name:	
Start/End date (must be one year or less):	
Associated Co-morbid diagnosis:	
MD Signature:	Date: