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

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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. Patients must have pharmacy benefits under their subscriber certificates.

Prior Authorization Information

☒ **Prior Authorization** ☒ **Step Therapy** ☒ **Quality Care Dosing**		**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289 Policy last updated **9/2023**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ **Rx** ☒ **MED**	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.
Policy applies to Commercial Members: • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary		**Blue Cross Blue Shield of Massachusetts** **Pharmacy Operations Department** 25 Technology Place Hingham, MA 02043 **Individual Consideration:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration

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®, direct-pay products such as Managed Major Medical, Comprehensive Managed Major Medical and certain Managed Blue for Seniors plans.

A complete list of BCBSMA non-covered drugs is available 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 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 may 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):[14,16] **NOT** Covered for those plans without 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.[17] 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, it's labeling (container label, package insert, and prescribing information leaflet), dosing and uses.[18]

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.[19] These unapproved uses are frequently called "off-label" uses. While it allows individual personal professional innovation, off-label prescription may discourage and may not be, 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.[17]

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.[17] "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)."[17] 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)."[20]

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 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 in investigational setting (i.e. Clinical Trial) or conditions[21] and or
- Inclusion in one or more CMS recognized compendia.[22,,23]

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.[22]

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. [22]

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.[23]

Drug Coverage Exclusions

We do not cover the following:

- Products that are not FDA-approved or that have no FDA-approved indications
- Medical Marijuana Products or non-FDA approved Cannabidiol (CBD) products
- Products that are available over-the-counter, unless specified in the subscriber certificate
- Procuren™, a growth factor for wound-healing, because it has not been conclusively proven to improve wound healing.[1] .
- 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
- Adipex P ®(phentermine), Redux ®(dexfenfluramine), Pondimin ®(fenfluramine), Lomaira ™(phentermine), which are part of the "Phen-Fen" combination) of which some 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 and these medications are written into the Subscriber Certificate as excluded.

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:
Ampyra™ (dalfampridine)	246	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 246 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 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	013	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 013 for details.
Anti-Migraine Policy	021	Prior authorization required for all plans. See Medical Policy 021 for details.
Anti-Parkinsonism Drugs	054	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 054 for details.
Antisense Oligonucleotide Medications	027	Prior authorization required for all plans
Asthma and Chronic Obstructive Pulmonary Disease Medication Management (Leukotrienes and Inhaled Combination Products)	011	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.
Benign Prostatic Hypertrophy (BPH)	040	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 040 for details.
Botulinum toxin	006	Prior authorization is required for all outpatient sites of service. See Medical Policy 006 for details.
Chlorhexidine	251	Coverage for chlorhexidine gluconate and Peridex (chlorhexidine gluconate) is limited to 1,440 mls in rolling 22 days or 4,320 in a rolling 67 days if using the mail order benefit.

Drugs that require prior authorization:	Document:	Coverage Note:
CNS stimulants and psychotherapeutic agents (Amphetamines)	019	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.
Compound Medications	579	Prior authorization required for all plans. See Medical Policy 579 for details.
Compound Medications Inclusion Drug List	704	No Prior authorization required for all plans. See Medical Policy 579 and 704 for details
Compound Medications Exclusion Drug List	705	Prior authorization required for all plans. See Medical Policy 579 and 705 for details.
COX II Inhibitor- Drugs	002	Prior authorization required for all plans. Smart logic edits may apply at Point-of-Sale. Quality Care Dosing limits apply. See Medical Policy 002 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®)	426	Prior authorization required for all plans. See Medical Policy 426 for details.
Diabetes Step Therapy – 2nd Step Agents	041	Prior authorization required for all plans. Step therapy edits apply at Point-of-Sale. See Medical Policy 041 for details.
Drugs for Cystic Fibrosis	408	Prior authorization required for Standard plans
Drugs for Weight Loss	572	Prior authorization required for Standard plans
Entyvio (vedolizumab) Policy	162	Prior authorization required for all plans. See Medical Policy 162 for details.
Erythropoietin, Recombinant Human [Epogen® (epoetin alfa), Procrit® (epoetin alfa) or Aranesp® (darbepoetin alfa)]	262	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	078	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	360	Prior authorization required for all plans. Covered only as a home infusion therapy benefit. See Medical Policy #360 for details.
Fentanyl, oral/transmucosal	113	Prior authorization required for Standard plans. Quality Care Dosing limits apply. See Medical Policy 113 for details.
Infertility Step Therapy	014	Step Therapy Policy requiring treatment failures before use of non-formulary medication. See Medical Policy 014 for details.
Growth hormone	257	Prior authorization required for all plans. See Medical Policy 257 for details.
Heart Failure and Hypertrophic Cardiomyopathy (HCM) Policy	063	Step Therapy Policy requiring treatment failures before use of non-formulary medication. See Medical Policy 063 for details.
Hepatitis C	344	Prior authorization required for all plans. See Medical Policy 344 for

Drugs that require prior authorization:	Document:	Coverage Note:
Medications		details.
Hetlioz (tasimelteon)	697	Prior authorization required for all plans. See Medical Policy 697 for details.
Home infusion therapy	430	Prior authorization required for all plans. All Medication for Home Infusion Therapy requires Prior Authorization. Note: Per diem not covered by Medex.
Hypoactive Sexual Desire Disorder (HSDD) Policy	131	Prior authorization required for all plans.
Injectable Asthma	017	Prior authorization required for all plans.
Injectable Specialty Medication Coverage	071	Drugs not covered under the medical benefit.
Immune Modulating Drugs	004	Prior authorization required for all plans. Step therapy edits apply. Quality Care Dosing limits apply. See Medical Policy 004 for details.
Immunoglobulins	310	Immunoglobulins
Immunomodulators, topical	010	Prior authorization required for all plans. See Medical Policy 010 for details.
Influenza Drugs	440	Covered at highest tier for a limited quantity.
Injections for osteoarthritis	427	Prior authorization required for all plans. See Medical Policy 427 for details.
Interferons (α,γ)	052	Prior authorization required for all plans. See Medical Policy 052 for details.
Massachusetts Standard Form for Prior Authorization Requests	434	Formulary Exception or Outpatient Retail Pharmacy Prior Authorization.
Medicare Part D Coverage Determination Request Form	442	Medicare Part D Coverage Determination Request Form
Medical Benefit Prior Authorization Medication List	034	List of medical Medications with Utilization Management (MedUM)
MedUM & Pharmacy Prior Authorization	033	Medical and Retail Pharmacy Prior Authorization required according to benefits. See Medical policy 033 for details.
Methotrexate Step Therapy	840	Step Therapy Policy requiring treatment failures before use of non-formulary medication. See Medical Policy 840for details
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.
Multiple Sclerosis Step Therapy	839	Step Therapy Policy requiring treatment failures before use of non-formulary medication. See Medical Policy 839 for details
Mupirocin Step Therapy	062	Step Therapy Policy requiring treatment failures before use of non-formulary medication. See Medical Policy 062 for details.
New Drug Approval Program	005	Applies to all plans. See Medical Policy 005 for details.
Non-covered Drug List	433	Applies to all plans with a closed formulary.
Nononcologic Uses of Rituximab	123	Medical and Retail Pharmacy Prior Authorization required according to benefits. See Medical policy 123 for details.
Oncology Drugs	409	Prior authorization required for all plans. See Medical Policy 409 for details.

Drugs that require prior authorization:	Document:	Coverage Note:
Ophthalmic Prostaglandin	346	Prior authorization required for all plans. Step therapy edits apply. See Medical Policy 346 for details.
Opioid Medication Management	102	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 102 for details.
Organ transplant rejection drugs: azathioprine (Azasan ®) basiliximab (Simulect ®) (Cellcept ®), cyclosporine (Imuran ®, Gengraf ®), everolimus (Zortress ®), Mycophenolate (Sandimmune ® or Neoral ®), mycophenolic acid (Myfortic ®), sirolimus (Rapamune ®), Tacrolimus (Prograf ®, Envarsus XR ®)	251	Prior authorization required only for Medex and Managed Blue for Seniors. Covered for transplants which were not a Medicare approved transplant. We will need the date of the transplant and the date of enrollment for Medicare Part A & Part B. Effective 12/21/00, lifetime coverage is provided for self-administered immunosuppressive drug therapy following a Medicare covered transplant [11,15]. Organ Transplant rejection Drugs Continued:
Overactive Bladder Medications	170	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	036	Prior authorization required for all plans. See Medical Policy 036 for details.
Pregabalin (Lyrica®)	057	Prior authorization required for all plans. See Medical Policy 057 for details.
Proton Pump Inhibitors	030	Prior authorization required for all plans. Quality Care Dosing limits apply. See Medical Policy 030 for details.
Quality Care Cancer Program (Medical Oncology)	099	Prior authorization required for all plans. See Medical Policy 099 for details.
Quality Care Dosing (QCD) Guidelines	621A	Quality Care Dosing (QCD) Guidelines.
Quality Care Dosing Guidelines Drug List	621B	Quality Care Dosing Guidelines Drug List
Repository Corticotropin Injection (Acthar)	064	Prior authorization required for all plans. See Medical Policy 064 for details.
Retail Pharmacy Prior Authorization Policy	049	Prior authorization required for all plans. See Medical Policy 049 for details.
Retinoic acid derivatives	251	Prior authorization required only for patients 30 years of age and older. Coverage for all ages is restricted to non-cosmetic purposes only. Under the state mandate for cancer drugs, FDA-approved

Drugs that require prior authorization:	Document:	Coverage Note:
		retinoids are covered for some active cancers, such as actinic keratosis.
RSV-Immunoprophylaxis	422	Prior authorization required for all plans.
Sickle Cell and Beta Thalassemia Policy	083	Prior authorization required for all plans. See Medical Policy 083 for details.
Soliris, Ultomiris, Myasthenia Gravis, PNH, and Neuromyelitis Optica Policy	093	Prior authorization required for all plans. See Medical Policy 093 Soliris, Ultomiris, and Neuromyelitis Optica Policy for details.
Special medical formulae/enteral feedings	304	Prior authorization required for all plans. See Medical Policy 304 for details.
Specialty Pharmacy List	051	Our Network of Specialty Pharmacies.
Spinal Muscular Atrophy (SMA) Medications	044	Prior authorization required for all plans. See Medical Policy 044 for details.
Sublingual Immunotherapy with Allergen-specific Extracts (SLIT)	681	Prior authorization required for all plans. See Medical Policy 681 for details.
Supportive Care Treatments for Patients with Cancer	105	Prior authorization required for all plans. See Medical Policy 105 for details.
Topical Testosterones	345	Prior authorization required for all plans. Step therapy edits apply. See Medical Policy 345 for details.
Total Parenteral Nutrition (TPN)	296	Prior authorization required for all plans. Covered only as a home infusion therapy benefit. Note: Per diem not covered by Medex.
Vascular Endothelial Growth Factor (VEGF) Inhibitors Step Therapy	092	Medical Prior Authorization required according to benefits. See Medical policy 092 for details.

Individual Consideration

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements.
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable.

- Clinical literature from reputable peer reviewed journals.
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
9/2023	Updated section on weight loss and updated IC to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
3/2023	Updated Careion links.
8/2022	Clarified Chlorhexidine gluconate criteria.
2/2022	Clarified transplant drug rejection list
1/2022	Updated to include new policies.
11/2020	Updated to include new policies.
7/2020	Updated to include new policies.
1/2020	Updated to include new and remove retired policies.
10/2019	Updated to include language on Medical Marijuana Products.
1/2019	Updated to include new and remove retired policies.
6/2018	Updated to include Specialty Pharmacy List
1/2018	Updated to remove retired policies.
9/2017	Updated to include new and remove retired policies.
6/2017	Updated to include new and remove retired policies and update Pharmacy Ops' address.
1/2017	Updated to include new and remove retired policies.
11/2016	Updated to remove retired policies.
6/2016	Updated to include new policies.
7/2015	Updated to include new policies and remove retired policies.
11/2014	Updated to include new policies and remove retired policies.
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® 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-α, TGF-β. 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-thromboglobin 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, Spancap, 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. AHCPR 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.*

15. 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.

16. 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
17. 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 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
18. Arch Intern Med. 2006;166:1021-1026
19. American Society of Hospital Pharmacists. ASHP statement on the use of medications for unlabeled uses. *Am J Hosp Pharm.* 1992; 49:2006–8.
20. Use of approved drugs for unlabeled indications. FDA Drug Bull. 1982; 12:4–5.
21. 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.
22. Drugs, unlabeled use Off-label drug use. BCBSA Policy 5.01.01. Archived 12/08/11.
23. Center for Medicare Advocacy. CMA Report: Medicare Coverage for Off-Label Drug Use. September 7, 2012
24. Compendia as Authoritative Sources for Use in the Determination of a "Medically Accepted Indication" of Drugs and Biologicals Used Off-Label in an Anti-Cancer Chemotherapeutic Regimen, Pub. 100-02 Medicare Benefit Policy, chapter 15, section 50.4.5.

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