

Overview of the BCBSRI Prescription Management Program

A. Prescription Drugs Dispensed at a Pharmacy

This plan covers prescription drugs listed on the Blue Cross & Blue Shield RI (BCBSRI) formulary and diabetic equipment or supplies bought from a pharmacy.

These benefits are administered by our Pharmacy Benefit Manager (PBM).

BCBSRI's formulary includes a tiered copayment structure and indicates that certain prescription drugs require preauthorization. If a prescription drug is not on our formulary, it is not covered. For specific coverage information or a copy of the most current formulary, please visit our website or call our Customer Service Department which is indicated at the end of section A in this document.

Prescription drugs and diabetic equipment or supplies are covered when dispensed using the following guidelines:

- the prescription must be medically necessary, consistent with the physician's diagnosis, ordered by a physician whose license allows him or her to order it, filled at a pharmacy whose license allows such a prescription to be filled, and filled according to state and federal laws;
- the prescription must consist of legend drugs that require a physician's prescription under law, or compound medications made up of at least one legend drug requiring a physician's prescription under law;
- the prescription must be dispensed at the proper place of service as determined by our Pharmacy and Therapeutics Committee. For example, certain prescription drugs may only be covered when obtained from a specialty pharmacy; and
- the prescription is limited to the quantities authorized by a physician not to exceed the quantity listed in the Subscriber Agreement Summary of Pharmacy Benefits.

Prescription drugs are subject to the benefit limits and the cost listed in the Subscriber Agreement Summary of Pharmacy Benefits

Prescription Drug Quantity Limits

BCBSRI limits the quantity of certain prescription drugs that can be obtained at one time for safety, cost-effectiveness and medical appropriateness reasons. Our clinical criteria for quantity limits are subject to our periodic review and modification.

Quantity limits may restrict:

- the amount of pills dispensed per thirty (30) day period;
- the number of prescriptions ordered in a specified time period; or
- the number of prescriptions ordered by a provider, or multiple providers.

Our formulary indicates which prescription drugs have a quantity limit and can be found on our website or by contacting our Customer Service Department which is indicated at the end of section A in this document.

Types of Pharmacies

Prescription drugs and diabetic equipment or supplies can be bought from the following types of pharmacies:

- Retail pharmacies. These dispense prescription drugs and diabetic equipment or supplies.
- Mail order pharmacies. These dispense maintenance and non-maintenance prescription drugs and diabetic equipment or supplies.
- Specialty pharmacies. These dispense specialty prescription drugs, defined as such on our formulary.

For information about our network retail, mail order, and specialty pharmacies, visit our website or call our Customer Service Department which is indicated at the end of section A in this document.

Designated Pharmacy

BCBSRI may limit the selection of a pharmacy to one (1) pharmacy, referred to as a Pharmacy Home Assignment. Members subject to this designation include, but are not limited to, members that have a history of:

- being prescribed prescription drugs by multiple providers;
- having prescriptions drugs filled at multiple pharmacies;
- being prescribed certain long acting opioids and other controlled substances, either in combination or separately, that suggests a need for monitoring due to:
 - quantities dispensed;
 - daily dosage range; or
 - the duration of therapy exceeds reasonable and established thresholds.

Prescription Drug Payment Structure

Our formulary includes a tiered copayment structure, which means the amount you pay for a prescription drug will vary by tier. See the Subscriber Agreement section Summary of Pharmacy Benefits for your copayment structure, benefit limits and the amount you pay.

When you buy covered prescription drugs and diabetic equipment and supplies from a retail network pharmacy, you will be responsible for the copayment and deductible (if any) at the time of purchase. You will be responsible for paying the lower of your copayment, the retail cost of the drug, or the pharmacy allowance.

Specialty prescription drugs are generally obtained from a specialty pharmacy. If you buy a specialty prescription drug from a retail network pharmacy, you will be responsible for a significantly higher out of pocket expense than if you bought the specialty drug from a specialty pharmacy.

The amount you pay for the following prescription drugs is not subject to the tiered copayment structure:

- Contraceptive methods;
- Over-the-counter (OTC) preventive drugs;
- Nicotine replacement therapy (NRT) and smoking cessation prescription drugs;
- Infertility specialty prescription drugs; and
- Covered diabetic equipment or supplies bought at a network pharmacy.

See the Subscriber Agreement Summary of Pharmacy Benefits for benefit limits and the amount you pay.

This plan allows for medication synchronization in accordance with R.I. General Law §27-18-50.1. This means a prorated copayment may be applied to qualifying covered prescription drugs used for chronic long-term conditions, when prescribed for less than a thirty (30) day supply and dispensed by a network pharmacy.

Generic Substitution

By Rhode Island law, Pharmacies are required to dispense the FDA approved non branded version of a brand name medication for which the originally issued drug patent has expired, unless the physician indicates in the applicable space on the prescription form “Brand Name Necessary”.

Therapeutic Interchange

This dispensing practice offers to utilize alternative drug products within the same therapeutic class as the originally prescribed medication, after obtaining the prescriber’s approval of the Interchanged drug. BCBSRI does not actively engage in this practice.

Prescription Drug Preauthorization

Prescription drug preauthorization is the advance approval that must be obtained before BCBSRI provides coverage for certain prescription drugs. Prescription drug preauthorization is not a guarantee of payment, as the process does not take benefit limits into account.

Services that require prescription drug preauthorization are marked with a (+) symbol in the Subscriber Agreement Summary of Pharmacy Benefits.

How to Obtain Prescription Drug Preauthorization

To obtain prescription drug preauthorization, the prescribing provider must submit a prescription drug preauthorization request form. These forms are available on BCBSRI.com, by calling the number listed for the “Pharmacist” on the back of the members ID card, or the provider can contact the Physician & Provider Service Center.

Prescription drugs that require preauthorization will initially be reviewed by pharmacists and authorized personnel (i.e. pharmacy technician) against plan provided criteria based on medical necessity. Upon initial review the authorized personnel may approve requests. All other requests that may potentially be denied must be reviewed by a physician reviewer that would make a final determination (either an approval or denial).

Requests will only be approved when our clinical guidelines are met. These guidelines are based upon clinically appropriate criteria that ensure that the prescription drug is appropriate and cost-effective for the illness, injury or condition for which it has been prescribed.

We will send both members and practitioners written notification of the prescription drug preauthorization determination (either an approval or denial) within fourteen (14) calendar days of the receipt of the request.

How to Request an Expedited Preauthorization Review

You may request an expedited review if the circumstances are an emergency. Due to the urgent nature of an expedited review, the prescribing provider must either call or fax the completed form and indicate the urgent nature of the request. When an expedited preauthorization review is received, we will respond in writing to both members and practitioners with a determination (either an approval or denial) within seventy-two (72) hours or less.

Formulary or Coverage Exception Process

When a prescription drug is not on our formulary, you can request that this plan cover the drug as an exception. To request a formulary or coverage exception a Coverage Exception form must be submitted. The form can be found on our website or by contacting our Customer Service Department which is indicated at the end of section A in this document. The prescribing provider can also submit the request for you. The provider should supply all relevant clinical information needed to establish medical necessity. Information can include any contraindications, allergies or history of adverse drug reactions to alternatives, and all medications that have been previously tried and failed for the treatment of this diagnosis

Requests for formulary or coverage exceptions are initially reviewed by pharmacists against criteria that establishes medical necessity. Upon initial review the pharmacists may approve requests. All other requests that may potentially be denied must be reviewed by a physician reviewer that would make final determination (either an approval or denial).

Requests will only be approved when our clinical guidelines are met. These guidelines are based upon clinically appropriate criteria that ensure that the prescription drug is appropriate and cost-effective for the illness, injury or condition for which it has been prescribed.

We will send both members and practitioners written notification of the prescription drug preauthorization determination (either an approval or denial) within fourteen (14) calendar days of the receipt of the request.

How to Request an Expedited Formulary or Coverage Exception Review

You may request an expedited review if a delay could significantly increase the risk to your health or your ability to regain maximum function, or you are undergoing a current course of treatment with a drug not on our formulary. Please indicate "urgent" on the Coverage Exception form or inform Customer Service of the urgent nature of your request. We will respond in writing to both members and practitioners with a determination (approval or denial) within twenty-four (24) hours following receipt of the request.

If we grant your request for a formulary or coverage exception, the amount you pay will be the copayment at the highest non-specialty formulary tier. Other applicable benefit requirements, such as step therapy, are not waived by this exception and must be reviewed separately.

Denials and Appeals

If a request results in a denial, the determination response will include the criteria upon which the request did not meet standard for approval. The response will also include an outline of the internal and external appeal process for when a request has not been approved. Members may also refer to Requests for Authorization, Denials of Benefits, Complaints, and Appeals section in the member subscriber agreement for information on how to file a medical appeal.

Appeal Requests can be sent to our Pharmacy Benefit Manager (PBM):

Prime Therapeutics, LLC.
Attn: Clinical Review Department
1305 Corporate Center Drive
Eagan, MN 55121
Fax #: 1.855.212.8110

Step Therapy

This process is often referred to as a type of prior authorization process which requires that one drug be used in treatment prior to another drug being allowed for coverage. The intention is that a member has tried or been treated with the first drug and a documented treatment failure or adverse reaction has resulted. In some cases the pharmacy claim system can be utilized to “look back” at claim activity to identify that a certain drug has been prescribed previously to satisfy the step therapy requirements.

Contact Information

BCBSRI Customer Service Department: 401.459.5000 or 1.800.639.2227
BCBSRI Website: www.bcbsri.com
BCBSRI Pharmacy Benefit Manager (PBM):
Prime Therapeutics, LLC.
Attn: Clinical Review Department
1305 Corporate Center Drive
Eagan, MN 55121
Fax #: 1.855.212.8110
Phone #: 1.855.457.0759

B. Prescription Drugs Administered by a Provider (Other Than a Pharmacy)

This plan covers prescription drugs dispensed and administered by a licensed healthcare provider (other than a pharmacy) with preauthorization. Coverage varies based upon how the prescription drug is administered, as described below.

When a prescription drug is provided through inhalation, nasal, ocular, oral, rectal, vaginal, sublingual, topical, or transdermal administration, coverage for the prescription drug is included in our allowance for the medical service being rendered. If the only service you receive is administration of the drug, the prescription drug is not covered.

When a prescription drug is administered by injection or infusion, this plan covers the prescription drug separately from the medical service being rendered. See the Subscriber Agreement Summary of Medical Benefits for benefit limits and the amount you pay.

Specialty prescription drugs are not separately reimbursed when dispensed by a professional provider unless bought from a network pharmacy.

C. Related Exclusions

- Biological products for allergen immunotherapy and vaccinations.

- Blood fractions.
- Compound prescription drugs that are not made up of at least one legend drug.
- Bulk powders and chemicals used in compound prescriptions that are not FDA approved, are not covered unless listed on our formulary.
- Prescription drugs prescribed or dispensed outside of our dispensing guidelines.
- Prescription drugs that have not proven effective according to the FDA.
- Prescription drugs used for cosmetic purposes.
- Prescription drugs purchased from a non-designated pharmacy, if a pharmacy has been designated for you through the Pharmacy Home Assignment program.
- Experimental prescription drugs including those placed on notice of opportunity hearing status by the Federal Drug Efficacy Study Implementation (DESI).
- Prescription drugs provided to you that are not dispensed by a network pharmacy or covered under your medical plan.
- Prescription drugs and diabetic equipment and supplies purchased at a non-network pharmacy unless indicated as covered in the Summary of Pharmacy Benefits.
- Prescription drug related medical supplies except for diabetic, regardless of the reason prescribed, the intended use, or medical necessity. Examples include, but are not limited to, alcohol pads, bandages, wraps or pill holders.
- Off-label use of prescription drugs except as described in Experimental or Investigational Services section;
- Prescribed weight-loss drugs.
- Replacement of prescription drugs resulting from a lost, stolen, broken or destroyed prescription order or refill.
- Therapeutic devices and appliances, including hypodermic needles and syringes except when used to administer insulin.
- Prescription drugs, therapeutic equivalents, or any other pharmaceuticals used to treat sexual dysfunctions.
- Vitamins, unless specifically listed as a covered healthcare service.
- A prescription drug refill greater than the refill number authorized by your doctor, more than a year from the date of the original prescription, or limited by law.
- Long acting opioids and other controlled substances, nicotine replacement therapy, and specialty prescription drugs when purchased from a mail order pharmacy.
- Prescription drugs and specialty prescription drugs when the required prescription drug preauthorization is not obtained.
- Certain prescription drugs that have an over-the-counter (OTC) equivalent.
- Prescriptions filled through an internet pharmacy that is not a verified internet pharmacy practice site certified by the National Association of Boards of Pharmacy.
- Illegal drugs, including medical marijuana, which are dispensed in violation of state and/or federal law.

D. Pharmacy and Therapeutics (P&T) Committee, Formulary Changes and Updates

Background

The development of the formulary is an ongoing and dynamic process that is under constant evaluation in response to marketplace events. New drug entities come to market every day, some in the form of FDA approvals of new products, reformulations of existing products, repackaged products, or drugs that are sold from one manufacturer to another. There is similar activity for both brand drugs and generic drugs. Drug products are also being removed from the market, some voluntarily and some by order of the FDA. The formulary process evaluation also includes monitoring of drug shortages and reacting to this

by adjusting the claims processing system in some cases to allow coverage of the brand product that has been excluded under the Blue Cross & Blue Shield of Rhode Island Formulary, as an example.

One critical component of formulary development and maintenance is the corporate Pharmacy & Therapeutics (P&T) Committee. This Committee is made up of local and independent physicians and pharmacists that provide clinical input and oversight to the content and structure to the Plan Formulary. In addition, it is the responsibility of the P&T Committee to conduct therapeutic class reviews on a revolving basis throughout the year to validate formulary coverage and review utilization within the class. The Committee also considers any updated and applicable clinical guidelines produced by nationally recognized compendia and academic review organizations such as the CDC, NHLBI, NCCN, and ASCO, ADA or similar groups.

Role of the P&T Committee

The P&T Committee meets according to a published schedule as necessary to meet its obligations and provides feedback based upon the clinical information presented. The Committee evaluates and discusses the specific recommendations made by the BCBSRI clinical staff in conjunction with the PBM clinical representative. The Committee is charged with clinical oversight of the proposed recommendations to ensure that they are consistent with medical practice.

Plan sponsored recommendations may include initial and changes to formulary tiering for drugs, application of prior authorization requirements, suggested quantity limits for the amount of drug allowed for a 30 day supply, and designations of drugs as meeting the requirements for distribution as a specialty drug.

The volume and volatility of marketplace activity and the need to respond in a timely manner to the real-time drug claim processing system create challenges. Given the limited schedule of P&T meetings, it became necessary to develop and adopt a process authorized by the Committee to allow the clinical staff to implement formulary actions outside of the normal committee review. These guidelines are referred to as the Formulary Guiding Principles. These guidelines provide direction to update the claims system based upon a standard set of principles. On a twice annual basis, all decisions regarding new drugs to market and the action taken since the last formulary update are reviewed by the full P&T Committee.

Development of Recommendations

Beyond the process of monitoring the current state, there is an active review process that seeks to identify opportunities for potential cost savings. This pre-P&T Committee, made up of the BCBSRI clinical pharmacy staff, Plan Medical Director and PBM clinical representatives consider new drugs to market in relation to existing products and review the clinical implication of the new drug options. A review of the clinical drug studies may identify advantages over available treatments or simply confirm that the drug is another product in the class that replicates existing therapy. The group reviews and identifies targets within the generic pipeline to anticipate marketplace reaction to a newly available generic within the therapeutic class. The group consults with the PBM on manufacturer rebate contracting implications of patent loss and the introduction of new products within the class. Formulary tier changes and the potential impact on manufacturer rebates are modeled by the PBM prior to the Committee meeting. The modeling identifies possible formulary placement and the corresponding changes in manufacturer rebates. The value of the rebates is weighed against the resulting member disruption, the appropriate access to medications, the changes in member out of pocket cost, and the potential increase in Plan claims expense.

The output or recommendations of the pre-P&T group will take these issues into account, when developing the recommendations for the full P&T Committee.

In preparation for the formal P&T Committee meeting, the clinical staff of both the Plan and PBM, along with BCBSRI Medical Director develops a meeting agenda of topics for consideration by the Committee. The agenda will include regularly scheduled therapeutic class reviews, identified opportunities for formulary changes, reaction to marketplace changes including price volatility, new drugs to market or significant changes in drug utilization. An agenda of topics along with a Plan recommended action is included with associated materials for distribution to the Committee prior to the meeting. Each agenda item is presented in detail and the Plan recommendation is debated and subject to adoption, modification or disapproval by the P&T Committee based upon the clinical merits. The Plan works within the clinical oversight and input provided by the Committee to make business decisions as deemed necessary.

Potential Agenda Topics for Pharmacy & Therapeutics Committee meeting:

1. Impending generic availability – impact on existing products in class.
2. Release of new clinical studies involving an important therapeutic class.
3. Contracting opportunities presented by PBM from manufactures for preferred status
4. Present information from a utilization review of drug classes suggesting the need for management in the form of a PA or Quantity Limit.
5. Identify a therapeutic class that has not been the subject of a full class review in the past 24 months and include it for the next scheduled P&T meeting.
6. Review of marketplace pricing updates to identify generics to be placed at tier 2 or moved to tier 1 in response to pricing declines.
7. FDA approvals of new drugs to market and expected patterns of use.

Implementation

The decisions of the P&T Committee form the basis of the twice annual formulary updates, scheduled in April and October. Each formulary update represents the cumulative decisions made by the Committee since the last update. In advance of the effective date of the changes, it is the Plan's practice to notify members 30 days in advance of any changes that may impact out-of-pocket expense or coverage.