# Pharmaceutical Management Procedures for the BCBSRI Prescription Program

## ***Definitions***

***DISPENSING GUIDELINES*** mean:

- the prescription order or refill must be limited to the quantities authorized by your *doctor* not to exceed the quantity listed in the Summary of Pharmacy Benefits;
- the prescription must be *medically necessary*, consistent with the *doctor's* diagnosis, ordered by a *doctor* 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 *doctor's* prescription under law or compound medications made up of at least one *legend drug* requiring a *doctor's* prescription under law; and
- 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 *provider*.

Quantity limits may apply. Some prescription drugs are subject to additional quantity limits based on criteria that we have developed. You may obtain a current list of prescription drugs that have been assigned maximum quantity levels for dispensing by visiting our Web site at BCBSRI.com or calling our Customer Service Department at (401) 459-5000 or 1-800-639-2227.

***FORMULARY*** means the prescription drugs and dosage forms covered under this *agreement.* Some prescription drugs are not in the *formulary*. If a prescription drug is not in our *formulary*, then it is not covered under this *agreement*. A committee of local physicians and pharmacists, set up by us, develop the prescription drug *formulary* listing which is subject to periodic review and is subject to change. The committee decides the tier placement of drugs in the *formulary*, which determines the amount you will pay. To obtain coverage information for a specific prescription drug or to get a copy of the most current *formulary* listing, visit our Web site at BCBSRI.com. Or, you may call our Customer Service Department at (401) 459-5000 or 1-800-639-2227 for information.

***LEGEND DRUG*** is a drug that federal law does not allow the dispensing of without a prescription.

**NETWORK PHARMACY** means any pharmacy that has an *agreement* to participate in the Catamaran National Pharmacy Network for prescription drugs and diabetic equipment/supplies covered under this *agreement.* All other pharmacies are **NON-NETWORK PHARMACIES**. The one exception and for the purpose of *specialty prescription drugs,* only specialty pharmacies that have an *agreement* to accept our *pharmacy allowance* are *network pharmacies* and all others pharmacies are *non-network pharmacies.*

***PHARMACY ALLOWANCE*** means the lower of:

- the amount the pharmacy *charges* for the prescription drug;
- the amount we or our PBM have negotiated with a *network pharmacy*; or
- the members benefit plan copayment

**PHARMACY BENEFIT MANAGER (PBM)** is our chosen vendor to provide services for the Prescription Drug Benefit Program. Our PBM is Catamaran of Illonois. They provide management of the Network Pharmacies, Claims Processing, Utilization Management and Manufacturer Contracting and Rebating programs.

***PRESCRIPTION DRUG PREAUTHORIZATION*** is the advance approval that must be obtained before we provide coverage for certain prescription drugs. *Prescription drug preauthorization* is not a guarantee of payment, as the process does not take benefit limits into account. The process for obtaining *prescription drug preauthorization* is described below.

You must ask the prescribing physician to request *prescription drug preauthorization* for certain preferred brand name and non-preferred brand name prescription drugs and certain specialty prescription drugs.

***SITE OF SERVICE*** means, for the purposes of this a*greement*, the three types of pharmacies which include:

- retail pharmacies,
- specialty pharmacies, and
- mail order pharmacy.

***SPECIALTY PRESCRIPTION DRUG*** is a type of prescription drug in our *formulary* that generally is identified by, but not limited to, features such as:

- being produced by DNA technology,
- treats chronic or long term disease,
- requires customized clinical monitoring and patient support, and
- needs special handling, such as temperature stability

Generally, specialty pharmacies dispense *specialty prescription drugs*. Contact Customer Service for further details and information about *specialty prescription drugs* and specialty pharmacies. For the purposes of this *agreement*, we have designated certain prescribed prescription drugs in our *formulary* to be *specialty prescription drugs.* To obtain coverage information for any specific *specialty prescription drug* or to obtain a copy of the most current *formulary* listing, visit our Web site at BCBSRI.com. Or, you may call our Customer Service Department at (401) 459-5000 or 1-800-639-2227.

***TYPE OF SERVICE*** means, for the purposes of this *agreement*, the two kinds of prescription drugs which are defined as:

- generic, preferred brand name, and non-preferred brand name prescription drugs;
- *specialty prescription drugs.*

## Overview

Prescription drugs and diabetic equipment and supplies bought at a pharmacy are administered by our Pharmacy Benefit Manager (PBM). Prescription drugs bought at a pharmacy are subject to the *benefit limits* and level of coverage shown in the Summary of Pharmacy Benefits.

Generic, preferred brand name, and non-preferred brand name prescription drugs dispensed and administered by a licensed health care *provider* (other than a pharmacy) are subject to the *benefit limit* and level of coverage shown in the Summary of Medical Benefits. *Specialty prescription drugs* are not separately reimbursed when dispensed by a professional *provider* unless bought from a Specialty Pharmacy.

## Pharmacy Program for Prescription Drugs and Diabetic Equipment/Supplies Purchased at a Pharmacy

### Introduction

This section provides coverage information for prescription drugs in our *formulary* generic, preferred brand name, and non-preferred brand name prescription drugs, *specialty prescription drugs* and diabetic equipment and supplies that are bought at a pharmacy. Prescription drugs must be identified as covered under this *agreement* in our *formulary* and dispensed per our *dispensing guidelines* in order to be covered.

Generic, preferred brand name, and non-preferred brand name prescription drugs may be dispensed at a retail pharmacy, a specialty pharmacy, a mail order pharmacy, or by a provider other than a pharmacy. *Specialty prescription drugs* must be dispensed at a specialty pharmacy or a *non-network pharmacy.* If a professional provider dispenses a *specialty prescription drug,* it is not separately reimbursed unless obtained from a specialty pharmacy. The administration of the *specialty prescription drug* is covered.

If you are dispensed a *specialty prescription drug* from a Rhode Island *network provider,* the charge for the *specialty prescription drug* is not reimbursed and the Rhode Island *network provider* may not seek reimbursement from you. If you are dispensed a *specialty prescription drug* from a *non-network provider* or by a *provider* that participates with an out of state Blue Cross or Blue Shield plan, the charge for the *specialty prescription drug* is not reimbursed. You are liable to pay the charge for the *specialty prescription drug*.

Prescription drugs are reimbursed based on the *type of service* and the *site of service*. See the Summary of Pharmacy Benefits for *benefit limits* and the amount that you pay.

Coverage for prescription drugs is subject to the pharmacy program. The pharmacy program's *formulary* includes a four-tier *copayment* structure and requires *prescription drug preauthorization* for certain prescription drugs. It also includes dose optimization conditions. Each of these items is described in more detail below. Coverage is provided for prescription drugs bought at a pharmacy, per the terms, conditions, exclusions, and limitations of this *agreement.*

**Four-Tier Copayment Structure**
This prescription drug plan *formulary* has a four-tiered *copayment* structure.

**First Tier:** includes *formulary* low cost generic prescription drugs, which require the lowest *copayment.*

**Second Tier:** includes *formulary* high cost generic prescription drugs and preferred brand name prescription drugs, which require a higher *copayment*.

**Third Tier:** includes *formulary* non-preferred generic and non-preferred brand name drugs which require a higher *copayment* than the Second Tier.

**Fourth Tier:** includes *formulary specialty prescription drugs,* which require a *copayment.*

Our *formulary* lists generic, preferred brand name, and non-preferred brand name prescription drugs and *specialty prescription drugs* covered under this *agreement.* We decide which tier a drug will be placed into for *copayment* purposes. To check the tier placement of a prescription drug or to obtain a copy of the most current *formulary* listing, visit our Web site at BCBSRI.com. Or, you may call our Customer Service Department at (401) 459-5000 or 1-800-639-2227.

**Generic Substitution**
By RI General 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.

**Mail Order Pharmacy**
Maintenance and non-maintenance generic, preferred brand name, or non-preferred brand name prescription drugs and diabetic equipment and supplies may be bought from the PBM mail order pharmacy. The prescription quantity supply is limited to the *benefit limit* and level of coverage shown in the Summary of Pharmacy Benefits. For mail order instructions, please call our Customer Service Department.

**Covered Diabetic Equipment/Supplies**
The following diabetic equipment and supplies can be bought at a *network pharmac*y:

- Glucometers;
- Test Strips;
- Lancet and Lancet Devices; and
- Miscellaneous Supplies (including calibration fluid).

See the Summary of Pharmacy Benefits for *benefit limits* and the amount that you pay.

**Covered over- the- counter (OTC) drugs**
Certain preventive over- the- counter (OTC) drugs when prescribed by a physician may be covered. To obtain a specific list of the OTC drugs that are covered, call our Customer Service Department or visit our website at www.bcbsri.com.

**Restricted Pharmacy**
We may limit your selection of a pharmacy to one (1) *network pharmacy*. *Members* subject to this restriction are those members that have been prescribed prescriptions by multiple physicians and have had prescriptions filled at multiple pharmacies. Contact our Customer Service Department for more information.

**How Covered Prescription Drugs and Diabetic Supplies/Equipment Are Paid**
When you buy covered prescription drugs and diabetic equipment and supplies from a *network* pharmacy, you will be responsible for the *copayment* and *prescription drug deductible* (if any) shown in the Summary of Pharmacy Benefits at the time you buy the prescription drugs and diabetic equipment and supplies. Coverage is based on our *pharmacy allowance*.

This *agreement* does NOT cover generic, preferred brand name, and non-preferred brand name prescription drugs or diabetic equipment and supplies when bought at *non-network pharmacies*. If you buy generic, preferred brand name, and non-preferred brand name prescription drugs or diabetic equipment and supplies from *non-network pharmacies*, you will be responsible to pay the charge for the prescription drug or diabetic equipment and supplies at the time the prescription is filled.

If you buy s*pecialty prescription drugs* from a retail *network pharmacy* or a *non-network pharmacy*, you will be responsible to pay the charge for the *specialty prescription drug* at the time the prescription is filled. You may submit a *claim* to us and we will reimburse you directly. You will be responsible for the *copayment* shown in the Summary of Pharmacy Benefits and the difference between the *charge* and the *pharmacy allowance*. See Section 7.1 - How to File a *Claim*.

**How to Obtain Prescription Drug Preauthorization**
*Prescription drug preauthorization* is required for certain brand name prescription drugs and certain *specialty prescription drugs*. To obtain *prescription drug preauthorization*, the prescribing *provider* must submit a completed *prescription drug preauthorization* request form.

The prescribing *provider* may obtain a *prescription drug preauthorization* form by visiting our Web site at BCBSRI.com or calling the Physician and Provider Service Center.

Preauthorization requests may be submitted in one of the following ways:
- By fax, submit the form to Catamaran at 1-866-391-7222;
- By phone, contact Catamaran at 1-866-235-3062;
- By mail, send the completed form to:

Catamaran
Prior Authorization Center
2441 Warrenville Road, Suite 610
Lisle, IL 60532-3642

Prescription drugs that require *prescription drug preauthorization* will only be approved when our clinical guidelines are met. The 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 to you written notification of the *prescription drug preauthorization* determination within two (2) business days of receipt of all medical documentation required to conduct the review, but not to exceed fourteen (14) calendar days from the receipt of the request.

**Note**: You may request an expedited review if the circumstances are an emergency. Due to the urgent nature of an expedited review, your prescribing *provider* must fax the completed form to 1-866-261-0453. If an expedited preauthorization review is received by us, we will respond to you with a determination within seventy two (72) hours following receipt of the request.

If you have not obtained *prescription drug preauthorization* before you pick up the prescription drug from the pharmacy for the first time, you can ask us to consider reimbursement later. To do this, you must follow the *prescription drug preauthorization* process described above and submit your request for review, along with a copy of your receipt, within fifteen (15) days of picking up the prescription. If our clinical guidelines are met for the prescription drug, we will approve your claim to be reimbursed retroactively less the applicable *copayment* or *deductible*.

To obtain a list of the brand name prescription drugs and *specialty prescription drugs* that require *prescription drug preauthorization*, visit our Web site at BCBSRI.com or call our Customer Service Department at (401) 459-5000 or 1-800-639-2227.

If you are not satisfied with the *prescription drug preauthorization* determination, you can submit a Medical Appeal. See Section 7.3 for information on how to file a Medical Appeal.

**Step Therapy**
This process is often referred to as a 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 patient 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.

**Related Exclusions**

The following items are NOT covered when obtained at a pharmacy:

- biological products for allergen immunotherapy;
- biological products for vaccinations;
- blood fractions;
- compound prescription drugs that are not made up of at least one *legend drug;*
- prescription drugs prescribed or dispensed outside of our *dispensing guidelines*;
- prescription drugs indicated as being not covered on our *formulary*;
- prescription drugs that have not proven effective according to the FDA;
- prescription drugs used for cosmetic purposes ;
- prescription drugs purchased in excess of the stated quantity limits;
- *experimental* prescription drugs (including those placed on notice of opportunity hearing status by the Federal Drug Efficacy Study Implementation (DESI);
- drugs you take or have given to you while you are a patient in a *hospital,* rest home, sanitarium, nursing home, home care *program*, or other institution that provides prescription drugs as part of its services or which operates its own facility for dispensing prescription drugs;
- non-medical substances (regardless of the reason prescribed, the intended use, or medical necessity);
- off-label use of prescription drugs (except as described in Section 3.11 *Experimental/Investigational* Services);
- over-the-counter (OTC) drugs even if prescribed, unless specifically listed as a *covered health care service* in this *agreement* ( such as, OTC nicotine replacement therapy in accordance with Rhode Island General Law 27-20-53,or as part of our OTC Options Program, or PPACA);
- OTC drugs designated as covered under this *agreement* for which you do not have a written prescription from your physician;
- prescribed weight-loss drugs;
- replacement prescription drug products resulting from a lost, stolen, broken or destroyed prescription order or refill;
- support garments and other durable medical equipment;
- therapeutic devices and appliances, including hypodermic needles and syringes (except when used to administer insulin);
- sildenafil citrate (Viagra) or any therapeutic equivalents; OR
- Vitamins specifically listed as a *covered health care service* in this *agreement*.

We will NOT cover a prescription drug refill if the refill is:

- greater than the refill number authorized by your *doctor;*
- greater than the twelve (12) refills we authorize;
- limited by law; or
- re-filled more than a year from the date of the original prescription.

The following are NOT covered when purchased from a *non-network pharmacy*:

- generic, preferred brand name, or non-preferred brand name prescription drugs; and
- diabetic equipment and supplies.

The following are NOT covered when purchased from a mail order pharmacy:

- *specialty prescription drugs*; and
- nicotine replacement therapy.
- certain designated classes of controlled substances are not allowed to be obtained from mail order.

Generic, preferred brand name, or non-preferred brand name prescription drugs and *specialty prescription drugs* are NOT covered when the required *prescription drug preauthorization* is not obtained.

Multiple daily doses of a generic, preferred brand name, or non-preferred brand name prescription drug are NOT covered when dose optimization conditions are not met.

Certain prescribed prescription drugs that have an over-the-counter equivalent (OTC) are NOT covered under this *agreement.* To obtain the list of OTC prescription drugs visit our Web site at BCBSRI.com or contact our Customer Service Department at (401) 459-5000 or 1-800-639-2227.

**B. Generic, Preferred Brand Name, or Non-Preferred Brand Name Prescription Drugs Dispensed and Administered by a Licensed Health Care *Provider* (other than a Pharmacy)**

Generic, preferred brand name, or non-preferred brand name prescription drugs we have approved that are dispensed and administered by a licensed health care *provider* (other than a pharmacy) are covered under this *agreement,* subject to the *copayment* and *deductible*( if any*)* shown in the Summary of Medical Benefits. The generic, preferred brand name, or non-preferred brand name prescription drug must be dispensed per our *dispensing guidelines* in order to be covered.

**C. Process for Communication of Pharmacy and Therapeutics (P+T) 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 Committee (P&T). 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 Pharmacy & Therapeutics Committee (P&T) 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**

The P&T Committee meets every other month throughout the year 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. A sub-group of the Committee along with Plan and PBM Clinical staff forms the Specialty P&T Committee which focuses on the marketplace introduction of new specialty drug products, often high cost biologics. This sub-group reports into the full P&T Committee on their activity.

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 an annual basis, all decisions regarding new drugs to market and the action taken regarding formulary coverage 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 decision points 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.