Horizon Blue Cross Blue Shield of New Jersey

PRESCRIPTION DRUG TIER EXCEPTIONS APPROVAL POLICY

	Property/Name	**Value**
1	**Policy Name**	Prescription Drug Tier Exceptions Approval Policy (Commercial)
2	**Policy Reference Number**	HCM-PP-PHAR-004-1220
3	**Department**	Pharmacy
4	**Current Effective Date**	01/01/21
5	**Next Recertification Date** *(Align with review frequency)*	12/01/21
6	**Owner (V.P. or Director level)**	Patrick Gill
7	**Director / Manager Responsible for Implementation**	Kavita K. Parmar
8	**Policy Coordinator**	Theresa Cunningham
9	**Name of Approving Committee**	MMC, PT
10	**Committee w/ Primary Oversight**	MMC, PT
11	**Prior Policy Name** *(if applicable)*	N/A
12	**Original Effective Date**	10/25/02
13	**Prior Revision Dates** *(up to last 5 years)*	06/27/08, 06/12/09, 05/21/10, 05/20/11, 05/18/12, 03/15/13, 03/21/14, 3/20/15, 11/20/15, 01/01/16, 11/18/16, 12/01/17, 12/14/18, 12/13/19, 12/11/20
14	**Review Frequency** *(1 or 2 years)*	1
15	**Web Portal Posting (Yes / No)**	Yes
16	**Approved By (Signature) and Date** *(for Program Descriptions only)*	N/A

IMPORTANT NOTE

This policy provides information applicable to the administration of outpatient prescription drug coverage that Horizon Blue Cross Blue Shield of New Jersey and Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ") issues or administers. ***Outpatient prescription drug coverage is not included in all Horizon benefit plans.*** *If the member's/covered person's contract benefits differ from a pharmacy policy, the contract prevails. Although a service, supply, drug or procedure may be medically necessary, it may be subject to limitations and/or exclusions under a member's/covered person's prescription drug coverage. If a service, supply, drug or procedure is not covered and the member proceeds to obtain the service, supply, drug or procedure, the member may be responsible for the cost.*

Decisions regarding treatment and treatment plans are the responsibility of the physician. This policy is not intended to direct the course of clinical care a physician provides to a member/covered person, and it does not replace a physician's or pharmacist's independent professional clinical judgment or duty to exercise special knowledge and skill in the treatment or provision of services to Horizon BCBSNJ members/covered persons. Horizon BCBSNJ is not responsible for, does not provide, and does not dispense prescription drugs nor hold itself out as a provider of medical care. The physician and/or pharmacist, as applicable, remains responsible for the quality and type of health care services provided to a Horizon BCBSNJ member/covered person.

Horizon BCBSNJ pharmacy policies do not constitute medical advice, authorization, certification, approval, explanation of benefits, offer of coverage, contract or guarantee of payment.

PURPOSE:

The purpose of this policy is to describe the process to be followed by members/covered persons who have prescription drug benefits with a drug based tier structure for obtaining coverage of a non-preferred drug at the preferred level of coverage, in accordance with all applicable state and federal law and regulations.

SCOPE:

This policy applies to the Commercial (EPO, OMNIA, Qualified Health Plans offered on and off the State-based exchange, PPO, DA, POS, HMO, Indemnity, FEP®, and ASO) plans issued and/or administered by Horizon Healthcare Services, Inc. d/b/a Horizon Blue Cross Blue Shield of New Jersey and/or its affiliates, including Horizon Healthcare of New Jersey, Inc. (collectively "Horizon BCBSNJ"). It applies to individuals covered under self-insured plans unless the administrator of the plan elects not to apply this policy to its prescription drug coverage.

PROCEDURE:

In many of its plans, Horizon BCBSNJ employs tiered co-payment structures in connection with its prescription drug benefits. When obtaining a prescription drug under a tiered co-payment structure, a member/covered person's co-payment will vary depending upon how the prescription drug is classified by the P & T Committee and whether it is considered a generic drug, preferred brand name drug or non-preferred drug. In the event a non-preferred brand drug or a multisource brand is determined to be medically necessary by the prescribing physician due to the ineffectiveness or documented intolerance to a preferred drug or a generic equivalent, a member/covered person or their health care provider may request that the drug be covered at the preferred drug level by following the process described below.

A non-preferred brand drug shall be deemed to be medically necessary and eligible for coverage at the preferred brand drug level if the health care provider certifies that:

1. It is approved under the Federal Food, Drug and Cosmetic Act;
2. For non-preferred brand or requests: The prescribing physician or healthcare professional states that at least two (2) preferred drugs or generic equivalents if two (2) or more are available, have been tried prior to the requested brand product used to treat the disease state have been ineffective in the treatment of the member/covered person's disease or condition, or all such drugs have caused or are reasonably expected to cause adverse or harmful reactions in the member/covered person, and medical records or other documentation that supports this view are supplied to the plan.
3. If approved, the requested brand name product will be covered at preferred brand level (tier 2)

A multisource non-preferred brand shall be deemed to be medically necessary and eligible for coverage at the preferred brand drug level if the healthcare provider certifies that:

1. It is approved under the Federal Food, Drug and Cosmetic Act;
2. For multisource brand requests: The prescribing physician or healthcare professional states that a generic equivalent has been tried prior to the requested brand product used to treat the disease state and it has been ineffective in the treatment of the member/covered person's disease or condition, or all such drugs have caused or are reasonably expected to cause adverse or harmful reactions in the member/covered person, and medical records or other documentation that supports this view are supplied to the plan.
3. If approved, the requested brand name product will be covered at preferred brand level (tier 2)

All such requests may be made either orally or in writing by the member/covered person or their health care provider on their behalf and should be directed to Horizon BCBSNJ's Pharmacy Benefit Manager (PBM) member services telephone number on the member/covered person's ID card. In the event such requests are made to other areas of Horizon BCBSNJ, they should be routed to Horizon BCBSNJ's Pharmacy Department. The PBM's member services department will request the necessary documentation, including the exception request form and/or the FDA MedWatch form, if available, from the member/covered person's health care provider and forward it to the appropriate personnel within the Horizon BCBSNJ's PBM Clinical Review department where a determination will be made.

Documentation must be provided by the prescribing physician demonstrating the medical necessity of the non-preferred brand drug or multisource brand drug based upon the requirements in this policy. Documentation shall include that portion of the member/covered person's medical record that indicates which drugs have been prescribed as well as the reactions or ineffectiveness of these drugs. This may be demonstrated by prior patient experience with similar drugs or classes of drugs. Documentation may be submitted via facsimile.

Once the appropriate information is received by Horizon BCBSNJ, a determination will be made and Horizon BCBSNJ shall respond to the member/covered person and/or the prescriber by telephone or other telecommunication device in accordance with the time frames established in the policy Time Frames for Notification of Determinations to Approve or Deny Coverage of Services, New Jersey Requirements. The time frames for initial determinations for expedited/urgent requests is within 24 hours from the time the request is made and for standard requests is within 72 hours from the time the request is made. Initial denials shall also be provided to the prescriber and the member/covered person in writing and shall be communicated in a culturally and linguistically appropriate manner as required under federal health care reform regulations (45 CFR 147.136(e), and include the clinical reason for the denial. A plan medical director licensed to practice medicine will perform and be responsible for issuing all denials. The plan medical director may be an employee of Horizon BCBSNJ, or may be an appropriately licensed employee of a contracted vendor performing such review in accordance with Horizon BCBSNJ's policies and procedures. In the event that the request is approved, the non-preferred drug will be covered at the appropriate preferred level depending upon whether the drug is a generic drug or a brand name drug.

Horizon BCBSNJ or its contracted vendor will maintain an on-call process for obtaining approval of the drugs in emergency situations 24 hours per day, 7 days per week. Denials are appealable pursuant to those procedures set forth in the member/covered person's contract, evidence of coverage or member handbook, including the right to appeal to the Independent Health Care Appeals Program offered through the Department of Banking and Insurance as applicable. The written denial letter shall also include a description of Horizon BCBSNJ's review procedures and the time limits applicable to such procedures, including instructions on how to initiate an appeal, information on how to initiate standard and expedited internal and, if applicable, external appeals and a statement of the claimant's right to bring a civil action under section 502(a) of ERISA, if applicable, upon completion of the internal appeals process; Further, the denial letter shall include a description of any additional information necessary for the determination to be reconsidered on appeal and an explanation why such material is necessary; and reference to the specific plan provision on which the determination is based. It shall also contain a notice of the right to have the diagnosis and treatment codes relevant to the case, if any, supplied to the member upon the member's request.

Horizon BCBSNJ Pharmacy Policy Development Process:

This Horizon BCBSNJ Pharmacy Policy (the "Pharmacy Policy") has been developed by Horizon BCBSNJ's Pharmacy Policy Working Group, Medical Management Committee, and Pharmacy and Therapeutics Committee, which include practicing physicians and pharmacists. This policy is consistent with generally accepted standards of medical and pharmacy practice, and reflects Horizon BCBSNJ's view of the subject health care services, supplies, drugs or procedures, and in what circumstances they are deemed to be medically necessary or experimental/ investigational in nature. This Pharmacy Policy also considers whether and to what degree the subject health care services, supplies, drugs or procedures are clinically appropriate, in terms of type, frequency, extent, site and duration and if they are considered effective for the illnesses, injuries or diseases discussed. Where relevant, this Pharmacy Policy considers whether the subject prescription drugs are being requested primarily for the convenience of the covered person or the health care provider. It may also consider whether the prescription drugs are more costly than alternative prescription drugs that are at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the relevant illness, injury or disease. In reaching its conclusion regarding what it considers to be the generally accepted standards of medical and pharmacy practice, Horizon BCBSNJ reviews and considers the following: all credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician and health care provider specialty society recommendations, the views of physicians and health care providers practicing in relevant clinical areas (including, but not limited to, the prevailing opinion within the appropriate specialty), the findings and directives of the Food and Drug Administration and any other relevant factor as determined by applicable State and Federal laws and regulations.

REFERENCES:

1. NJSA 17B:30-48
2. NJAC 11:22-5.7
3. NCQA – Current Standards and Guidelines for the Accreditation of Health Plans.

Pharmacy Policies can be highly technical and are designed for use by the Horizon BCBSNJ professional staff in making coverage determinations. Members referring to this policy should discuss it with their treating physician or pharmacist, and should refer to their specific benefit plan for the terms, conditions, limitations and exclusions of their coverage.

This Horizon BCBSNJ Pharmacy Policy is proprietary. It is to be used only as authorized by Horizon BCBSNJ and its affiliates. The contents of this Pharmacy Policy are not to be copied, reproduced or circulated to other parties without the express written consent of Horizon BCBSNJ. The contents of this Pharmacy Policy may be updated or changed without notice, unless otherwise required by law and/or regulation. However, benefit determinations are made in the context of Pharmacy Policies existing at the time of the decision and are not subject to later revision as the result of a change in Pharmacy Policies.