

MEDICAL NECESSITY DETERMINATION POLICY FOR PRESCRIPTION DRUGS

	Property/Name	Value
1	Policy Name	Medical Necessity Determination Policy for Prescription Drugs (Commercial)
2	Policy Reference Number	HCM-PP-PHAR-001-1220
3	Department	Pharmacy
4	Current Effective Date	01/01/21
5	Next Recertification Date <i>(Align with review frequency)</i>	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 <i>(if applicable)</i>	N/A
12	Original Effective Date	01/23/04
13	Prior Revision Dates <i>(up to last 5 years)</i>	06/12/09, 06/18/10, 05/20/11, 05/18/12, 03/15/13, 03/21/14, 03/20/15, 11/20/15, 01/01/16, 11/18/16, 12/01/17, 12/14/18, 12/13/19, 12/11/20
14	Review Frequency <i>(1 or 2 years)</i>	1
15	Web Portal Posting (Yes / No)	Yes
16	Approved By (Signature) and Date <i>(for Program Descriptions only)</i>	N/A

SUBJECT: MEDICAL NECESSITY DETERMINATION POLICY FOR PRESCRIPTION DRUGS

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.

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.

PURPOSE:

The purpose of this Policy is to set forth the policy and procedure for the process used by Horizon BCBSNJ in making a medical necessity determination for prescription drugs or categories of prescription drugs to which medical necessity applies. In instances where the medical necessity for a requested drug is reviewed and medical necessity not demonstrated as described below, a written adverse benefit determination notice is issued with appeal rights provided, and the requested drug will not be covered by the plan. In such instances, the member may elect to pay for the drug themselves and/or appeal the adverse benefit determination.

POLICY:

I. Coverage under Horizon BCBSNJ benefit plans is limited to services, including covered drugs and supplies, which Horizon BCBSNJ determines to be medically necessary as defined by the plan documents. Certain drugs selected by Horizon BCBSNJ will be subjected to a medical necessity determination process for review as described herein if the member's contract provides for such a program. Drugs that have a prior authorization requirement will be subjected to the Pharmaceutical Prior Authorization process (see policy: Pharmaceutical Prior Authorization Policy).

A listing of the drugs that are subject to a medical necessity determination process is posted on Horizon's contracted Pharmacy Benefits Manager's (PBM) myPrime web site and available upon request from Horizon BCBSNJ Pharmacy Services.

II. The medical necessity determination process shall be initiated in one of three ways. They are as follows:

A. **Point of Service:** Drugs that are subject to this Medical Necessity Determination Policy are automatically subjected to on-line edits at the participating pharmacies at the point of service. The pharmacist will receive an electronic message at the point of service advising that he/she or the member should contact the contracted pharmacy benefit manager (PBM) to initiate the medical necessity determination process. The prescriber may contact the PBM to initiate medical necessity determination process instead of the pharmacist or member.

B. **Prior to point of service:** A request for medical necessity determination prior to the point of service at the pharmacy may be initiated as indicated below:

A. The prescriber of the medication may contact the contracted PBM by telephone, fax, mail, or e-prescribing prior to prescribing the drug.

If approved, an edit will be added to the pharmacy system to indicate that a Medical Necessity Determination has been approved. Member and provider receive a determination letter noting the outcome of the review. For adverse determinations, members and providers are given the appeal rights for next steps.

C. **After drug is dispensed:** When pharmacies, prescribers or members submit a claim directly to PBM for reimbursement after the product has been dispensed and paid for out of pocket by the member/covered person or their provider, a medical necessity determination may take place either prior to claims payment or in a post-payment audit.

III. **Time Frames: PBM** will 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 entitled, "Time Frames for Notification of Determinations to Approve or Deny Coverage for Services, New Jersey and Medicare requirements." The initial determination turn-around-times for medical necessity reviews are within 24 hours from the time the request for review is made for urgent/expedited requests and within 72 hours from the time the request for review is made for standard requests.

IV. Process: The documentation for the medical necessity determination process must contain specific details about the member's medical condition and treatment plan, sufficient to establish that the patient's medical circumstances meet the criteria. In cases where this cannot be established, additional documentation must be presented that clearly establishes the medical necessity for use of the drug in doses or quantities above the approved drug dispensing limits, for use in non-FDA approved age or gender categories, for use outside the approved therapeutic parameters, or for any use outside of the required criteria.

- The prescriber of the medication must complete a request or write a letter detailing the medical necessity of the drug for the member/covered person's condition.

Once the appropriate information necessary to make the Medical Necessity Determination decision is received by PBM, the documents will be reviewed by a clinical pharmacist who may approve the request, if it meets applicable utilization management criteria, request additional information from the prescriber requesting the service, or refer the request to the Medical Director. The clinical pharmacist may be an employee of Horizon BCBSNJ or its affiliates, or may be a contracted delegate performing in accordance with Horizon BCBSNJ's policies and procedures. The pharmacist may approve the request after review and consideration of the following available clinical information, evaluation of the individual health needs of the patient, consideration of the characteristics of the local delivery system, and if necessary, consultation with the physician coordinating the patient's care, as properly documented in the medical record. If the information gathered does not meet the relevant medical necessity criteria and thus fails to establish medical necessity, the pharmacist will document the medical necessity criteria that was not met and/or other specific reasons for the potential denial. A plan medical director, or an authorized delegate who is also a Medical Director, will review the request and all submitted documentation and render a medical necessity determination decision.

The plan medical director may be an employee of Horizon BCBSNJ or its affiliates or subsidiaries, or may be a contracted delegate performing in accordance with Horizon BCBSNJ's policies and procedures. If additional information is required, the pharmacist or plan medical director, or authorized designee will contact the prescriber for the additional information. The medical director or designee may approve the request following review of the available clinical information, evaluation of the individual health needs of the patient, consideration of the characteristics of the local delivery system, and if necessary, consultation with the physician coordinating the patient's care, as properly documented in the record. In all cases where the medical director or designee's review results in a decision which is adverse to the member, the medical director will make the final medical necessity decision within the time frame established in the policy entitled "Time Frames for Notification of Determinations to Approve or Deny Coverage for Services, New Jersey" as noted above.

Any response denying the requested prescription drug based on a medical necessity determination will be confirmed by a adverse benefit determination written notice, communicated in a culturally and linguistically appropriate manner as required under federal health care reform regulations (45 CFR 147.136(e)), and containing the following:

1. The reason for the adverse determination including the clinical rationale, if any;
2. 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;
3. Notice of the availability of the clinical review criteria relied upon to make such determination;
4. A description of any additional information necessary for the determination to be reconsidered on appeal and an explanation about why such material is necessary; and reference to the specific plan provision on which the determination is based.
5. 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

The member/covered person, authorized representative, or prescriber, (on the member's behalf and with the member's written consent), may file an appeal of any denial based on medical necessity pursuant to those procedures set forth in the member/covered person's subscriber contract, evidence of coverage or member handbook, including, if applicable, the right to appeal to the Independent Health Care Appeals Program offered through the Department of Banking and Insurance, if applicable. Any such appeals will be handled in accordance with the applicable member appeals policy for the appropriate product.

Horizon BCBSNJ works collaboratively with Prime Therapeutics LLC to create and update the utilization management criteria for individual prescription drugs. All such utilization management criteria are reviewed on at least an annual basis.

Prime Therapeutics LLC also provides monthly and quarterly utilization management data to Horizon. These reports provide high level utilization data as well as drug/drug category specific utilization data. The reports also include statistics on coverage requests, approvals and denial rates, and denial rationale for drugs/drug categories. Based on the feedback analysis of the reported data, as well as the available published medical literature, the utilization management criteria are updated when appropriate. The utilization reports are also presented to the Medical Management Committee for its review.

This Horizon BCBSNJ Pharmacy Policy (the "Pharmacy Policy") has been developed by Horizon BCBSNJ's Pharmacy Policy Working Group, and the Pharmacy and Therapeutics Committee, which includes practicing physicians and pharmacists. Oversight of all Pharmacy Policy also occurs through the Quality Improvement Committee-

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.

REFERENCE:

NJAC 11:24-8.1 et seq
NJAC 11:24-4.11, NJAC 11:24-4.12

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.