Department:	Pharmacy Management	**Original Approval:**	10/23/2006
Policy No:	PM554	**Last Approval:**	05/26/2026
Policy Title:	Coverage Determinations and Exceptions Policy		
Approved By:	Clinical Services Leadership Team		
Dependencies:	None		

Purpose

This policy describes the manner in which Community Health Plan of Washington (CHPW) reviews coverage determinations and exception requests for Medicare Part D coverage from a member; a member's authorized representative, or a member's physician in accordance with Centers for Medicare & Medicaid Services (CMS) requirements.

Policy

CHPW and its delegated entities must provide timely coverage determinations and exceptions requests in accordance with CMS requirements. Coverage exceptions cannot be requested for drugs that are excluded from coverage under Part D (Non-Part D drugs), such as smoking cessation and weight loss products. A standard procedure is in place for making coverage determinations or exceptions, and an expedited procedure exists for situations in which applying the standard procedure may seriously jeopardize the enrollee's life, health, or ability to regain maximum functioning.

CHPW has contracted with a Pharmacy Benefit Manager (PBM) as its delegated entity for managing coverage determinations and exceptions requests for all CHPW enrollees. The PBM is responsible for ensuring that network pharmacies post or distribute notices informing enrollees of the right to obtain a coverage determination or request an exception. Additionally, the PBM is responsible for written notification to members of the right to redetermination using CMS-approved forms. CHPW has the authority to monitor the PBM's reliability in meeting CMS requirements with regard to coverage determinations and exceptions. CHPW maintains final authority and responsibility for all coverage determinations and exceptions.

Coverage Determinations

Coverage determinations are classified as any determinations (i.e., an approval or denial) made by or on behalf of CHPW regarding payment or benefits to which a member believes he or she is entitled. Coverage determinations include:

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

1. A decision about whether to provide or pay for a Part D drug (including a decision not to pay because the drug is not on the plan's formulary, because the drug is determined not to be medically necessary, because the drug is furnished by an out-of-network pharmacy, or because the Part D plan sponsor determines that the drug is otherwise excluded under section 1862(a) of the Act if applied to Medicare Part D) that the member believes may be covered by the plan;

2. A decision concerning a tiering exceptions request under 42 CFR 423.578(a);

3. A decision concerning a formulary exceptions request under 42 CFR 423.578(b);

4. A decision on the amount of cost sharing for a drug; or

5. A decision whether a member has, or has not, satisfied a prior authorization or other utilization management requirement.

Standard Determinations
A member, a member's representative, or a member's prescriber may request a standard coverage determination. If the request involves a Part D drug benefit that a member has not received yet, the request may be filed with the PBM via phone or in writing via mail or fax.

The PBM has processes in place to accept coverage determinations requests and supporting documentation 24 hours a day, 7 days a week (including holidays).

Requests for reimbursement of benefits the member has already received must be filed in writing to the PBM. If a member attempts to request reimbursement by phone, the PBM will explain the procedures the member must follow to file a written request for reimbursement.

Time Frames for Standard Coverage Determinations

- Requests for Part D drug benefits that has not been received
    - The member and the prescribing physician (or other prescriber involved, as appropriate) are notified of the determination as expeditiously as the member's health condition requires, but no later than 72 hours after the date and time the request for a standard coverage determination is received, or no later than 72 hours after receiving the physician's or other prescriber's supporting statement, if the request involves an exception.
- Requests for reimbursement for a Part D drug benefit that has been received

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

  - If the decision is unfavorable, the PBM must make the decision and provide notice of the decision no later than 14 calendar days after receiving the reimbursement request.
  - If the decision is favorable, the PBM must make the decision, provide notice of the decision, and make payment no later than 14 calendar days after receiving the reimbursement request.
- When a reimbursement request requires a statement from a prescriber, the 14 calendar-day timeframe for processing a reimbursement request is not tolled pending receipt of a prescriber's supporting statement.

In cases where a supporting statement from the prescriber is required, the PBM will outreach to the prescriber and attempt to collect all necessary documentation to make a determination. The PBM will allow the prescriber a reasonable amount of time to respond to the request for a statement. If the PBM cannot obtain all relevant documentation within a reasonable timeframe, it will make its decision based upon the evidence available.

If the PBM does not make its decision timely, the case file will be forwarded to the Independent Review Entity for review and notify the member within 24 hours of the expiration of the adjudication time frame.

Whenever the PBM expects to issue a partially or fully adverse medical necessity decision based on initial review of the case, a licensed pharmacist reviews the case and makes the final determination.

Notifications

The PBM arranges with a network or preferred pharmacies to provide members with a written copy of the standardized pharmacy notice when the member's prescription cannot be filled under the Part D benefit and the issue cannot be resolved at the point of sale. The notice instructs the member on how to contact the PBM and explains the member's right to receive, upon request, a coverage determination (including a detailed written decision) from the PBM regarding their Part D prescription drug benefits, including information about the exceptions process. The PBM arranges with their network pharmacies (including mail-order and specialty pharmacies) to distribute the notice to members. The pharmacy notice is provided to the member if the pharmacy receives a transaction response indicating the claim is not covered by Part D and the designated NCPDP response code is returned. This notice must also be provided by the Mail Order Pharmacies and Home Infusion Pharmacies.

The PBM must provide written notice of any favorable or adverse decision it issues. The written notification must be easily understandable to the member and provide the specific reason for the denial. The content of the notice of denial text should strike a balance between

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

patient comprehension and the prescriber need for disclosure of criteria requirements. Acronyms must be written out the first time they appear in a notice of denial (e.g., Centers for Medicare and Medicaid Services [CMS]). The letter must include, but is not limited to, a description of any applicable Medicare coverage rule or any other applicable Part D plan policy upon which the denial decision was based, including any specific formulary criteria that must be satisfied for approval. If the drug could be approved under the exception rules, the denial notice must explicitly state the need for a prescriber's supporting statement and clearly identify the type of information that should be submitted when seeking a formulary or tiering exception.

Additionally, the PBM may make its initial notification orally so long as it also mails a written follow-up decision within 3 calendar days of the oral notification.

- If a member files the request, notice must be provided to the member.
- If a member has identified a representative, the PBM will send the written notice to the member's representative instead of the member.
- If a member's prescribing physician or other prescriber files a request on behalf of a member, the PBM will notify both the prescriber and the member. The member must receive written notice of the decision. The PBM is not required to provide a member's prescribing physician or other prescriber with a written follow-up decision after providing oral notice to the physician or other prescriber.

Expedited Determinations

When the member's urgent health needs require a more prompt coverage determination than is described above, a member, their representative, or the member's prescriber, may request that the PBM expedite a coverage determination when the member or their prescriber believe that waiting for a decision under the standard time frame may place the member's life, health, or ability to regain maximum function in serious jeopardy. Requests for an expedited review are not denied, as stated in the PBM's Policy Medicare-CD-02.

Time Frames for Urgent Coverage Determinations

In this case the outcome is communicated to the member or the member's representative within 24 hours after the request is made. This does not include requests for payment of Part D drugs already furnished. If the member is not notified of the determination within 24 hours, the complete case file is forwarded to the Independent Review Entity contracted by CMS and the member notified within 24 hours of the expiration of the initial 24-hour adjudication time frame.

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

Notifications
When the PBM issues a favorable decision, it will provide notice of its decision as expeditiously as the member's health condition requires, but no later than 24 hours after receiving the request.

If the PBM issues an adverse decision, in whole or in part, the PBM may make its initial notification orally no later than 24 hours after receiving the request, as well as providing a written decision notification within 3 calendar days of the oral notification.

The same letter content applies as outlined under Standard Determinations.

Processing Requests
CHPW promotes such fax, phone, and mail locations as specified by the PBM for receiving and managing coverage determination and exception requests. Enrollees can obtain this information from the following website, http://healthfirst.chpw.org/for-members/prescription-coverage/requesting-exceptions-and-coverage-determinations.

PBM Oversight
On a daily basis, CHPW reviews a report provided by the PBM of all coverage determinations and exceptions requests which were in progress or completed on the previous day. CHPW reviews the following elements of all unfavorable decisions and a sample of favorable decisions for compliance with CMS requirements as well as CHPW and PBM policies:

- The request is made by either the member, their prescriber, or the member's appointed representative. If a representative is appointed the PBM ensures appropriate documentation is retrieved before accepting the request.
- Time elapsed from receipt of request (or prescriber's statement when needed) to member notification is less than either 24 or 72 hours as appropriate for the urgency of the case.
- If a supporting statement is required from the prescriber, the PBM makes sufficient outreach attempts and allows the prescriber a reasonable amount of time to respond before making a determination with the information available.
- If the prescriber does not respond to reasonable requests for information from the PBM, CHPW will take appropriate action as necessary, according to prescriber contracting.
- Decisions are made accurately based on CMS approved coverage criteria and take into account all available information, including prescriber's statements and claims data.
- Written notification of the decision is provided timely within 3 days of verbal notification
- Written notification of unfavorable decisions explains the complete reason for the denial, the criteria for approval, explanation of rights to a redetermination and the

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

process for requesting one, accurate member information, and is easily understood by the member.

- If the PBM is unable to make a determination within the appropriate turnaround time, they forward the case to the IRE and notify the member within 24 hours of the missed deadline. An exception to the IRE forwarding requirement is allowed if a favorable determination is made and notification to the member provided within 24 hours of the expiration of the timeframe (PBM use of this exception must be rare).
- Denial Notices include adequate rationales with correct and complete information specific to the denial.
- Denial Notices are written in a manner easily understandable to enrollees.

List of Appendices

A. Detailed Revision History

Citations & References

CFR	42 CFR Subpart M	
WAC	284-43-5642	
RCW		
LOB & Contract Citation	☐ **WAHIMC**	
	☐ **BHSO**	
	☐ **Wraparound**	
	☐ **SMAC**	
	☐ **HH**	
	☐ **AHE**	
	☒ **MA/DSNP**	Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance
	☐ **CS**	
Other Requirements		
NCQA Elements	UM 11	
References		

Revision History

SME Review:	10/26/2006; 06/13/2007; 06/25/2008; 01/12/2009; 08/20/2009; 09/09/2009; 04/21/2010; 03/14/2011; 03/30/2012; 02/21/2013; 01/02/2014; 01/13/2015; 03/15/2016; 03/01/2017; 03/02/2018;

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

	10/12/2018; 10/01/2019; 02/25/2020; 08/20/2020; 06/07/2021; 05/27/2022; 06/07/2023; 06/13/2024; 06/24/2025; 05/26/2026
Approval:	09/09/2009; 04/30/2010; 03/23/2011; 04/04/2012; 04/19/2013; 04/23/2014; 03/11/2015; 03/18/2016; 03/14/2017; 03/13/2018; 10/19/2018; 11/13/2019; 08/28/2020; 07/21/2021; 05/31/2022; 06/07/2023; 06/13/2024; 07/01/2025; 05/26/2026

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

Appendix A: Detailed Revision History

Revision Date	Revision Description	Revision Made By
10/26/2006	Original	Rachel Koh
06/13/2007	Minor formatting changes	Rachel Koh
06/25/2008	Content Change	Rachel Koh
01/12/2009	Review for style and format	Sunny Otake
08/20/2009	Content Update	Jennifer Mui
09/09/2009	Approval	MMLT
09/09/2009	Reformat and edit for clarity	Jennifer Carlisle
04/21/2010	Content Update – PBM Oversight	Eric Guyette
04/30/2010	Approval	MMLT
03/14/2011	Content Update	Maria Chan
03/23/2011	Approval	MMLT
03/30/2012	Review. No changes	Eric Guyette
04/04/2012	Approval	MMLT
02/21/2013	Content Update	Maria Chan
04/19/2013	Approval	MMLT
01/2/2014	Content Update	Annie Lam
04/23/2014	Approval	MMLT
01/13/2015	Content update with input from INTCG	Lauren Pope
03/11/2015	Approval	MMLT
03/15/2016	Updated citations table. Minor text updates. Merged with PM 554	Mary Eckhart
03/18/2016	Approval	MMLT
03/01/2017	Moved to new template	Mary Eckhart
03/14/2017	Approval	MMLT
03/02/2018	Moved to new template	Mary Eckhart
03/13/2018	Approval	MMLT
10/12/2018	Language added to PBM oversight section regarding oversight of denial notice language	Yusuf Rashid
10/19/2018	Approval	MMLT
10/01/2019	Content update	Ivan Figueira, PharmD
11/13/2019	Approval	MMLT
02/25/2020	Reviewed. Citations table updated.	Rebecka Braband
08/20/2020	Edit to notification section regarding use of acronyms in notice of denials	Yusuf Rashid
08/28/2020	Approval	CMO Cabinet
06/07/2021	Reviewed. No Changes.	Rebecka Braband

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.

07/01/2021	Approval	Omar Daoud
07/21/2021	Approval	CMO Cabinet
05/27/2022	Reviewed, no changes. Approval	Omar Daoud
05/31/2022	Approval	CMO Cabinet
06/07/2023	Reviewed, no changes	Omar Daoud
06/07/2023	Approval	Clinical Services Leadership Team
06/13/2024	Reviewed, no changes	Omar Daoud
06/13/2024	Approval	Clinical Services Leadership Team
06/24/2025	Reviewed, no changes	Omar Daoud
07/01/2025	Approval	Clinical Services Leadership Team
05/26/2026	Reviewed, no changed	Omar Daoud
05/26/2026	Approval	Clinical Services Leadership Team

Data contained in this document is considered confidential and proprietary information and its duplication, use, or disclosure is prohibited without prior approval of Community Health Plan of Washington.