HEALTH PLAN PROCEDURE	
Title: Coverage Determination Oversight and Monitoring	**Number:** DMPHR02 **Revision:** E
Department: Medical Management	**Sub-Department:** Pharmacy
Applicable Lines of Business: ☐ Children's Health Insurance Plan ☒ Medicare ☐ Commercial Insured ☐ Non Insured Business ☐ Health Insurance Exchange ☐ USFHP ☐ Medicaid	
Effective Date: 05/09/2018	
Revision Date(s): 04/10/2019, 04/27/2020, 04/16/2021, 03/29/2022, 10/23/2023	

PURPOSE:

This procedure provides direction on oversight and monitoring to ensure decisions made regarding medication coverage and in accordance with CHRISTUS Health Plan's formulary.

DEFINITIONS AND ACRONYMS:

- **Appointment of Representative (AOR)** – A form (AOR Form-CMS 1696) that may be used by a member to appoint a specific person as their representative to allow them to receive/give information or to start requests on the member's behalf. Form-CMS 1696 may not be used to appoint an authorized representative for the purposes of enrollment and disenrollment.
- **Authorized Representative** – An individual appointed by an enrollee who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the member resides may allow, in order to execute an enrollment or disenrollment requests, filing a grievance, requesting a coverage determination, or in dealing with any of the levels of the appeals process. e.g., court appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under state surrogate consent laws, provided they have the authority to act for the member in this capacity (see 42 CFR 435.923).
- **Centers for Medicare and Medicaid Services (CMS)** – The federal agency responsible for administering the Medicare and Medicaid programs as well as the federally facilitated Marketplace.
- **Coverage Determination** – Any decision made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled. Types of coverage determinations:
    - Prior Authorization (PA) - Always Applies to All Members (Type 1 PA)
    - PA New Starts - Only-Applies to Members Not Currently Taking the Drug (Type 2 PA)
    - PA BvD - to determine if covered under Part D or Part B Medicare Benefit (Type 3 PA) - Administrative PA
    - Quantity Limit Exception (Type 1 is Maximum MDD, Type 2 is Quantity Over Time, morphine milligram equivalent (MME))
    - Step Therapy
    - Tiering Exception
    - Non-Formulary Exception
    - PA Exception
    - Step Therapy Exception

- Direct Member Reimbursement (DMR)

- **Effectuation –** Payment of a claim, authorization or provision of a benefit the plan sponsor has approved, or compliance with a complete or partial reversal of a Part D plan sponsor's original adverse coverage determination.
- **Enrollee** – A person who is eligible for coverage and is enrolled in Medicare and/or Medicaid.
- **Formulary –** A listing of medications covered under an enrolled member's prescription drug benefit implemented in accordance with requirements set forth by the Centers for Medicare and Medicaid Services (CMS).
- **Independent Review Entity (IRE) –** An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.
- **Pharmacy Benefits Manager (PBM)** – A third party company that functions as an intermediary between a health plan and pharmaceutical manufacturers. PBMs create formularies, negotiate rebates (discounts paid by a drug manufacturer to a PBM) with manufacturers, process claims, create pharmacy networks, review drug utilization, and occasionally manage mail-order specialty pharmacies.
- **Prescriber's Supporting Statement** – A supporting statement provided by a physician or other prescriber is entitled to great weight when reviewing the exception or other coverage determination request. The supporting statement must indicate that alternative drugs would not be as effective as the requested drug and/or would have adverse effects.
- **Redetermination –** The first level of the appeal process, which involves a Part D plan sponsor re-evaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained.
- **Tier –** Typically, each Plan's formulary is organized into tiers, and each tier is associated with a set copay amount. Most formularies have between 3 and 6 tiers. The lower the tier, the lower the copay amount. For example, Tier 1 might include all of the Plan's preferred generic drugs, and each drug within this tier might have a copay of $5–10 per prescription. Tier 2 might include the Plan's preferred brand drugs with a copay of $40–$50, while Tier 3 may be reserved for non-preferred brand drugs which are covered by the plan at a higher copay level - perhaps $70–$100. Tiers 4 and higher typically contain specialty drugs, which have the highest copays because they are generally quite expensive.
- **Utilization Management (UM)** – UM shall refer to any clinical, safety, or cost containment edits applied to formulary drugs including but not limited to Prior Authorization (PA), Step Therapy (ST), and Quantity Limits (QL).

PROCEDURE:

The following describes CHRISTUS' oversight process of the Pharmacy Benefit Manager (PBM) delegated function of Coverage Determinations (CD). CHRISTUS delegates the initial coverage determination process to the PBM.

A. CHRISTUS downloads the "daily" report from the PBM's reporting system of all Coverage Determinations that were initiated and completed by the PBM during the prior 30 days. Reports are titled "CD Oversight Report MM-DD-YY to MM-DD-YY downloaded on MM-DD-YY" with the first date being the beginning start date of the coverage determinations and the second date being the

last start date for coverage determinations included in the report. The final date is the date the report was downloaded from the PBM's reporting system.

B. CHRISTUS has assigned a pharmacy technician to download and review the coverage determination report weekly. A second pharmacy staff will be trained as a back-up when the primary technician is unavailable.

C. CHRISTUS reviews 5 coverage determinations on a weekly basis to ensure the PBM is compliant with CMS guidance and regulations. The reviewer will select a variety of cases including but not limited to approvals, denials and exception requests.

D. CHRISTUS' review and findings identified during the review are documented on the report "CD Oversight Report MM-DD-YY to MM-DD-YY downloaded on MM-DD-YY". The reviewer consults the pharmacist on inappropriate clinical-decision making and follow up action(s) for findings of non-compliance if uncertain how to handle the specific situation.

E. The review will focus on, but is not limited to:

1. Validation of accuracy of CD start date/time
2. Valid requestor
   a. Verify an AOR is on file for coverage determinations requested by someone other than the member or prescriber. (ex. If a spouse requests a CD on behalf of the member, CHRISTUS must have an AOR or similar legal document on file for this to be a valid request).
3. Appropriate Categorization/Classification
   a. Verify correct classification of exceptions requests versus prior authorizations or step therapy requests
   b. Verify request was classified correctly as standard versus expedited
      1) CMS generally expects CD requests related to the MME edit to meet the criteria for an expedited review
4. Validation of accuracy of the receipt date/time of prescriber supporting statement for exception requests
5. Appropriate application of exception policies, CMS approved UM criteria and references as applicable
6. Validation of timely decisioning
   a. Expedited case decisioned within 24 hours of receipt of the request for PA/ST or after receiving the prescriber's supporting statement for exceptions
   b. Standard case decisioned within 72 hours of receipt of the request for PA/ST or after receiving the prescriber's supporting statement for exceptions
   c. DMR request decisioned within 14 calendar days of receiving the request.
   d. Exception requests can be tolled generally up to 14 calendar days after receipt of an exception request to attempt to gain a supporting statement from a prescriber
   e. For untimely cases, validation of IRE auto-forward for denials and for approvals if not approved within 24 hours of the expiration date/time, used sparingly.
7. For Approvals, validation of effectuation based on CMS approved PA criteria or CHRISTUS'

policy for exception approval durations

a. Verification the effectuation was entered into the adjudication system prior to the expiration date/time of the request

b. Correct duration of approval entered in adjudication system

c. For untimely cases, validation of IRE auto-forward if not effectuated within 24 hours of the expiration date/time of the approval, used sparingly.

8. For DMR approvals, approval and verification payment was sent to the member timely. For DMR denials, the notification was sent timely.

   a. For approvals, payment and notification is required to be sent to the member within 14 calendar days after receiving the request.

   b. For denials, member notification occurred within 14 calendar days after receiving the request.

   c. If DMR requires a prior authorization or exception approval prior to approving the DMR, was the PA or exception request processed accordingly?

9. Sufficient outreach to the prescriber for cases that were denied

   a. Three (3) outreach attempts are required using different modalities (i.e. telephone, fax, written). Cases should include outreach attempts at different times of the day during business hours and on different days.

   b. Consideration for outreach attempts for cases that will elapse over the weekend or early on Monday must have more outreach on Thursday or Friday when the prescriber's office is open. CMS expects prescribers to be paged as necessary. If a prescriber is non-responsive, CMS expects Sponsors to have process in place for accountability and outreach.

10. Verification of timely member notification

    a. Was oral notification or good faith attempt completed timely?

    b. If no oral notification, was the written notification mailed within the required timeframe?

    c. If oral notification occurred, was the written notification mailed within 3 calendar days of the oral notification?

    d. Expedited Cases:

       1) Notification must occur within 24 hours of receipt of the request for PA/ST or after receiving the prescriber's supporting statement for exceptions.

    e. Standard Cases

       1) Notification must occur within 72 hours of receipt of the request for PA/ST or after receiving the prescriber's supporting statement for exceptions.

       2) Notification, and payment as applicable, for DMR requests must occur within 14 calendar days of receiving the request (DMR requests cannot be expedited).

11. Appropriate member and prescriber written notification - verification includes:

    a. Correct member name

    b. Correct name of medication

    c. Correct prescriber (if applicable)

d. Approval Letters:

1) Contains the duration of approval

2) Contains the conditions of the approval, if applicable (ex. CMS-approved QL if approved only for prior authorization criteria)

e. Denial Letters:

1) Letter contains the specific reason for the denial (i.e. if criteria was not met, what criteria is needed for an approval and/or what criteria did the member not meet).

2) Letter is written in language that is easy for the member to understand

3) Letter includes the member's appeal rights to request a redetermination if desired

F. Each Coverage Determination Case reviewed is assigned one of the following:

1. Pass – the elements noted above were found to be compliant with CMS guidance including but not limited to: appropriate requestor, correct coverage determination type, effectuation entered correctly, member and prescriber notification is correct, appropriate use of CMS approved criteria, or CMS compliant for NF, QL, ST and PA exception.

2. Pass with comments – No issues of non-compliance were identified during the review however there were other issues/discrepancies noted during the review.

3. Fail - One or more of elements reviewed were found to be non-compliant. This includes but is not limited to: requestor is not a prescriber, member, or member's appointed representative, incorrect coverage determination type, case not decisioned timely, effectuation entered incorrectly, member or prescriber notification is incorrect or untimely, CMS criteria is not appropriately utilized and/or case is not CMS compliant for NF, QL, ST or PA exception. The reviewer will document the element(s) found to be non-compliant on the report.

G. Cases marked as "Pass with Comment" are sent to the CHRISTUS Pharmacist and, if needed, to the PBM for review and response depending on the nature of the findings.

H. All cases marked as "Fail" are sent to the CHRISTUS Pharmacist and PBM for immediate correction and documented on the issue tracking log compiled by CHRISTUS. CHRISTUS requests a root cause analysis and corrective action plan (CAP) from the PBM for each failed case or specific root cause. The failed cases are also discussed at the coverage determination oversight meetings between CHRISTUS and the PBM.

I. The following actions are completed for each failed case:

1. For members that received an incorrect denial, the remediation activities include reopening and approving the coverage determination. Member outreach is conducted and documented as appropriate.

2. For incorrect written notification, the remediation activities include resending an accurate written notification to the member and prescriber, if applicable, with a cover letter stating the previous letter contained inaccurate information regarding the coverage determination.

3. For incorrect effectuations, the remediation activities include immediately updating the effectuation in the adjudication system. If the member received a rejected claim after the CD was approved with no subsequent paid claim, member outreach is conducted and documented.

J. A summary of the reviews and findings is tracked and reported to compliance on a quarterly basis.

REFERENCES:

- Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (Released December 2019)

RELATED DOCUMENTS:

- Health Plan Pharmacy Benefits Management Oversight Policy (MPHR03)
- CHRISTUS Part D Coverage Determination Training Manual

REVISION HISTORY:

Revision	Date	Description of Change	Committee
New	05/09/2018	Initial release.	Executive Leadership
A	04/10/2019	Annual review. Updated References with new Medicare guidance that merged Chapters 13 & 18.	Executive Leadership
B	04/27/2020	Annual review. No change to content. Made minor grammar corrections.	Executive Leadership
C	04/16/2021	Annual review. No change to content.	Executive Leadership
D	03/29/2022	Annual review. Updated references in accordance with CMS.	Executive Leadership
E	10/23/2023	Annual review. Updated purpose statement, definitions, related documents, and formatting.	Executive Leadership