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| Policy: | MA.6114 |
| Title: | **Medicare Part D Redeterminations** |
| Department: | Medical Management |
| Section: | Pharmacy Management |
| *CEO Approval:* | */s/ Michael Hunn 11/22/2024* |
| Effective Date: | 03/01/2017 |
| Revised Date: | 11/01/2024 |
| Applicable to: | ☐ Medi-Cal<br>☒ OneCare<br>☐ PACE<br>☐ Administrative |

## I. PURPOSE

This policy describes CalOptima Health's process for appeals of drug benefit coverage and/or payment of drug benefits for Medicare Part D.

## II. POLICY

A. A Redetermination consists of a review of an adverse Coverage Determination, the evidence and findings upon which it was based, and any other evidence that the parties submit or that is obtained by CalOptima Health.

B. Who May Request a Redetermination:

1. Member;
2. Member's Prescriber; or
3. Member's Authorized Representative.

C. With respect to Redeterminations, Members have the following rights:

1. The right to a timely Redetermination;
2. The right to an expedited Redetermination, subject to the provisions of this Policy;
3. The right to request and receive appeal data from CalOptima Health;
4. The right to receive notice when a request is forwarded to the Independent Review Entity (IRE);
5. The right to a reconsideration by the IRE if CalOptima Health upholds the original adverse determination in whole or in part; and

6. The right to request, and be given timely access to, the Member's case file and a copy of that case file, subject to federal and state law regarding confidentiality of patient information. CalOptima Health shall not charge the Member for providing a copy of the case file.

D. The CalOptima Health medication appeals process shall only pertain to fully adverse and partially adverse Coverage Determinations (CDs).

E. CalOptima Health shall make a Redetermination within the time frames defined within this Policy.

1. If additional information is required, CalOptima Health shall make reasonable and diligent efforts to obtain the necessary information within the defined time frames from sources which may include, but are not limited to, the Prescriber, the Member, and other healthcare Providers.

2. If the necessary information is not available within the defined time frames, CalOptima Health shall make its determination based upon the evidence that exists, if any.

3. If a Medicare Part D Redetermination is not made within the defined time frames, CalOptima Health shall auto-forward the request to the IRE.

F. CalOptima Health shall accept Redetermination requests and Prescriber Supporting Statements in the following formats:

1. Telephone;

2. Mail;

3. Facsimile; and

4. CalOptima Health shall not require a written request or a supporting statement to be provided on a specific form.

G. Subject to the provisions of this Policy, CalOptima Health shall notify a Member, a Member's Authorized Representative, and a Member's Prescriber of the Redetermination outcome in writing and, in some cases, verbally.

H. CalOptima Health's Medical Director shall be responsible for ensuring the clinical accuracy of all Redeterminations involving medical necessity. The Medical Director shall be a physician with a current license to practice medicine in the state of California.

1. A physician with sufficient medical expertise and knowledge of coverage criteria shall review partially or fully adverse medical necessity Redetermination decisions.

2. The physician must have a current and unrestricted license to practice within the scope of his or her profession in the state of California.

I. Member Notification

1. CalOptima Health shall maintain a List of Covered Drugs (Formulary), including restrictions such as quantity limit (QL), prior authorization (PA), and Step Therapy (ST) requirements, and shall make the Formulary available to Members on its Website. Members may also request a mailed copy of the Formulary.

2. CalOptima Health shall provide Members with information about the Redetermination process, including how to contact CalOptima Health, in the Evidence of Coverage and Member Handbook.

J. All Member-facing materials shall be reviewed and approved by CMS, consistent with CalOptima Health Policy MA.2001: Marketing Material Standards.

K. CalOptima Health shall make appeals data available to CMS upon request.

## III. PROCEDURE

A. Requesting a Redetermination

1. A Member, a Member's Authorized Representative, a Member's Prescriber or staff of Prescriber's office acting on the Prescriber's behalf, or a Provider may submit a Redetermination request verbally, or in writing, indicating the request to be either "standard" or "expedited."

    a. A Member's Authorized Representative shall submit a valid signed Form CMS-1696 or other equivalent notice to CalOptima Health.

    b. CalOptima Health shall include a copy of the original signed Form CMS-1696 or other equivalent notice or conforming written instrument with each new request for a Redetermination.

    c. CalOptima Health shall not require the Member to sign a new form for the life of the Redetermination, or for any new Redetermination filed by the Authorized Representative within one (1) calendar year from the date that a valid form was executed.

2. A Redetermination request for services that have already been furnished shall not be expedited.

3. A Redetermination request shall be made verbally or in writing within the following time frames:

    a. Medicare Part D Redeterminations shall be requested within sixty-five (65) calendar days after the date of the Notice of Coverage Determination.

    b. CalOptima Health may accept a request for Redetermination filed after the limits have been exceeded if the Member submits a request for an extension of the time frame for good cause. This request shall be made in writing and shall state the reason that the request for Redetermination was not filed on time.

B. Requesting an Expedited Redetermination

1. A Member, a Member's Authorized Representative, a Member's Prescriber or staff of Prescriber's office acting on the Prescriber's behalf, or a Provider may request CalOptima Health to expedite a Redetermination if waiting for a standard Redetermination may seriously jeopardize the Member's life, health, or ability to regain maximum function.

2. CalOptima Health shall not accept any request to expedite a Redetermination for drugs already furnished to the Member.

3. CalOptima Health shall provide an expedited Redetermination if:

    a. A request to expedite is made or supported by a Prescriber and the Prescriber indicates, either verbally or in writing, that applying the standard time for making a determination may seriously jeopardize the life or health of the Member or the Member's ability to regain maximum function; or

    b. A request to expedite is made by a Member or Member's Authorized Representative and CalOptima Health finds that the Member's health, life, or ability to regain maximum function may be seriously jeopardized by waiting for a standard Redetermination.

4. If CalOptima Health denies a request to expedite a Redetermination, CalOptima Health shall proceed as follows:

    a. Transfer and process the request under the standard Redetermination procedures as set forth in this Policy.

    b. Provide the Member or Member's Authorized Representative and the Prescriber with prompt verbal notice of the denial that:

        i. Explains that CalOptima Health shall process the request within the standard Redetermination time frame;

        ii. Informs the Member of the right to file an expedited grievance if he or she disagrees with CalOptima Health's decision not to expedite the Redetermination;

        iii. Informs the Member of the right to resubmit a request for an expedited Redetermination with the Prescriber's support; and

        iv. Provides instructions about CalOptima Health's expedited grievance process and time frames.

        v. Deliver a written notice, equivalent to the verbal notice described in Section III.B.4.b. of this Policy, to the Member or Member's Authorized Representative and the Prescriber within three (3) calendar days after providing verbal notice.

C. If CalOptima Health makes a fully or partially favorable decision:

1. CalOptima Health shall effectuate the authorization retroactive to the date of the first request made during the contract year, or retroactive to the date of service indicated in the request, whichever comes earlier.

2. For an Exception request, the coverage duration of the approval shall be for the remainder of the contract year.

3. For a Non-Exception request, the coverage duration of the approval shall be consistent with the duration specified in the formulary prior authorization criteria as calculated based on the date the decision is made. If the criteria does not specify the coverage duration, then the coverage duration shall be for the remainder of the plan year.

4. The coverage duration applies so long as:

    a. The Prescriber continues to prescribe the drug;

b. The drug continues to be considered safe for treating the Member's disease or medical conditions; and

c. The Member's enrollment period has not expired.

5. CalOptima Health shall not require the Member to request approval for a refill, or a new prescription, to continue using the approved drug after the refills for the initial prescription are exhausted, subject to the provisions of this Policy.

6. CalOptima Health shall provide notification to the Member or the Member's Authorized Representative and the Prescriber (as applicable), as described in Section III.H. of this Policy.

D. If CalOptima Health makes a fully or partially unfavorable decision, CalOptima Health shall provide notification to the Member or the Member's Authorized Representative and the Prescriber (as applicable), as described in Section III.H. of this Policy.

E. Time Frames for Completing Redeterminations

1. Standard Prospective Request

a. CalOptima Health shall complete the Redetermination, notify the Member or Member's Authorized Representative and the Prescriber, and effectuate the decision, if applicable, as expeditiously as the Member's health condition requires, but no later than seven (7) calendar days after the date CalOptima Health received the request.

2. Expedited Prospective Request

a. CalOptima Health shall complete the Redetermination, notify the Member or Member's Authorized Representative and the Prescriber, and effectuate the decision, if applicable, as expeditiously as the Member's health condition requires, but no later than seventy-two (72) hours after the date and time CalOptima Health received the request.

3. Retrospective Request

a. CalOptima Health shall complete the Redetermination and notify the Member or Member's Authorized Representative and the Prescriber no later than fourteen (14) calendar days after the date CalOptima Health received the request.

b. If applicable, CalOptima Health shall authorize payment for the benefit within fourteen (14) calendar days after the date CalOptima Health received the request.

c. If applicable, CalOptima Health shall make payment (i.e., mail the payment) no later than thirty (30) calendar days after the date CalOptima Health received the request.

4. Time Frame for review shall not be extended for Medicare Part D requests.

5. Auto-forward

a. If CalOptima Health does not make a decision, or fails to provide notice of the decision, in the applicable time frame, then within twenty-four (24) hours of the expiration of the adjudication time frame CalOptima Health shall:

i. Forward the request and case file to the IRE for review; and

ii. Notify the Member that the decision was not made timely and that their request is being forwarded to the IRE, utilizing the "Notice of Case Status" instead of the adverse decision notice described in Section III.H.2. of this Policy.

iii. If CalOptima Health discovers the untimely decision or notification more than twenty-four (24) hours after the expiration of the adjudication time frame, then CalOptima Health shall forward the request to the IRE and provide the Member with the "Notice of Case Status" as quickly as possible, not to exceed one (1) business day after discovery.

iv. If CalOptima Health's decision was fully favorable and was made soon after the expiration of the adjudication time frame (within one (1) business day), then CalOptima Health shall not forward the request to the IRE nor provide the Member with the "Notice of Case Status."

F. Request for Additional Information

1. When CalOptima Health does not have all the information needed to make a coverage decision, CalOptima Health shall make reasonable and diligent efforts to obtain all necessary information, including medical records and other pertinent documentation, from the Member's Prescriber.

2. CalOptima Health shall make a minimum of one (1) attempt to obtain additional information within the applicable adjudication time frame.

3. Whenever possible, CalOptima Health shall use multiple means of communication, including:

   a. Telephone;

   b. Fax;

   c. E-mail; and/or

   d. Standard or overnight mail with certified return receipt.

4. The sufficiency of CalOptima Health's outreach efforts is determined on a case-by-case basis and are contingent upon the facts and circumstances of each case.

5. CalOptima Health shall document all requests for information and maintain that information with the case file. The documentation must include:

   a. A specific description of the required information;

   b. The name, phone number, fax number, e-mail and/or mailing address, as applicable, for the point of contact at CalOptima Health; and

   c. The date and time of each request, documented by date and time stamps on copies of a written request, call record, facsimile transmission or e-mail. Call records should include specific information about who was contacted, what was discussed/requested, and what information was obtained by CalOptima Health.

6. Requests for information shall be made in a manner that increases the likelihood of making contact with the Prescriber and receiving the information.

a. When possible, requests for additional information shall be made during normal business hours in the Prescriber's time zone. However, outreach must not be limited to business hours when the time frame is limited.

b. CalOptima Health shall leverage its contractual relationship when the request involves the need for information from a contracted Provider.

7. The first request for information shall be made within the time frames indicated in the table below.

| ➔ Priority | Standard Request | Expedited Request |
|---|---|---|
| **Medicare Part D** | Two (2) Calendar Days | Twenty-four (24) hours |

8. When deemed necessary on a case-by-case basis, network Prescribers who do not respond to requests for required additional information may be referred to CalOptima Health's Medical Director for review.

G. Redetermination Decision

1. CalOptima Health shall designate one (1) or more individuals, other than the person involved in making the initial Coverage Determination, to review the Redetermination.

2. If CalOptima Health based the original adverse Coverage Determination on a lack of medical necessity, a physician with expertise in the field of medicine that is appropriate for the requested service shall review the Redetermination.

3. The reviewing physician making the Redetermination need not, in all cases, possess the same specialty or subspecialty as the Member's prescribing physician.

H. Notification Standards

1. Written notification of a fully favorable decision must be written in a manner that is understandable to the Member and explain the conditions of the approval, including but not limited to:

a. The duration of an approval;

b. Limitations associated with an approval; and/or

c. Any coverage rules applicable to subsequent refills.

2. Written notification of a fully or partially unfavorable decision must be specific to each individual case, written in a manner that is understandable to the Member, and provide:

a. The specific reason for the denial that takes into account the Member's presenting medical condition, disabilities, and special language requirements, if any;

b. 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;

c. Information on the Member's right to a Reconsideration;

d. The Member's plan identification number, the plan name, the contract identification number, and the Formulary identification number.

3. Written notification is required for all Redetermination decisions pertaining to Medicare Part D benefits.

4. CalOptima Health may make its initial notification orally so long as it also mails a written follow-up decision within three (3) calendar days of the oral notification. However, if a good faith effort was made but CalOptima Health is not able to provide verbal notice, written follow-up decision will be sent within the adjudication time frame. Oral notifications must satisfy the same requirements as written notifications, as described in Sections III.H.1 and III.H.2. of this Policy. For standard Redetermination decisions pertaining to Medicare Part D, a written notice will be mailed to the Member no later than seven (7) calendar days from the date the request was received.

5. When CalOptima Health has the Member's telephone number on file and relies on it to provide oral notice, but is unable to reach the Member, its good-faith effort to provide oral notice satisfies the notification requirement if:

   a. The good-faith effort is documented in writing and included in the case file;

   b. Written notice of the decision is sent to the Member within the adjudication time frame; and

   c. CalOptima Health is not at fault for its inability to reach the Member by phone.

6. When the Member's telephone number and/or mailing address is invalid or missing, CalOptima Health shall make a reasonable and diligent effort to obtain it, such as outreach to the Prescriber and/or dispensing pharmacy, if known, to request it. The outreach efforts shall be documented in writing and included in the case file.

7. Written notification to the Prescriber, as applicable, shall be communicated via facsimile.

   a. CalOptima Health shall document a copy of the notice, the date and time of facsimile transmission, and the final processing status of the transmission (successful or failed) in the case file.

   b. If the facsimile transmission is not successful, CalOptima Health shall attempt to resend the facsimile and/or outreach to the Prescriber to obtain a working fax number and provide verbal notification of the decision.

8. Written notification to the Member or Member's Authorized Representative, as applicable, shall be communicated via postal mail. Letters shall be mailed in accordance with the delegated downstream entity and CalOptima Health facility mailing procedures.

9. Notification of the results of the Medicare Part D Redetermination shall be provided to the Member, the Member's Authorized Representative, and/or the Member's Prescriber as indicated in the table below.

| ➔ Requestor<br>🡻 Notification to… | Member | Member's Representative | Member's Prescriber |
|---|---|---|---|
| **Member** | Required | Optional | Required |
| **Member's Representative** | Optional | Required | Optional |
| **Member's Prescriber** | Optional | Optional | Required (written notice is not required if oral notice is provided) |

I. Documentation and Reporting

1. CalOptima Health's Customer Service Department shall track oral Redetermination requests made by a Member or the Member's Authorized Representative in CalOptima Health's core system. CalOptima Health's Customer Service Department shall document in the core system, at a minimum, the date of receipt of a request for a Redetermination.

2. CalOptima Health's Pharmacy Management Department shall track written Redetermination requests made by a Member or Member's Authorized Representative in the Redeterminations Database.

3. CalOptima Health's Pharmacy Management Department shall track verbal and written Redetermination requests made by Prescribers and other Providers in the Redeterminations Database.

4. CalOptima Health is responsible for reporting certain data related to Redetermination requests, as described on CMS' Plan Reporting and Oversight webpage and on CMS' Program Audits webpage.

## IV. ATTACHMENT(S)

A. Notice of Case Status (OneCare) H5433_23PD040
B. Appointment of Representative Form (CMS-1696)

## V. REFERENCE(S)

A. Applications from Medicare Advantage Prescription Drug Plans (MA-PD) Sponsors
B. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
C. CalOptima Health Policy MA.2001: Marketing Material Standards
D. Prescription Drug Benefit Manual, Chapter 6, Part D Drugs and Formulary Requirements, Revised January 19, 2016.
E. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Effective July 19, 2024
F. Social Security Act, §§ 1860D-2, 1860D-43, and Section 1862
G. Title 42, Code of Federal Regulations (C.F.R.), Part 423, Revised October 1, 2011
H. Federal Register, April 23, 2024, Vol 89, No. 79

## VI. REGULATORY AGENCY APPROVAL(S)

None to Date

## VII. BOARD ACTION(S)

| Date | Meeting |
|---|---|
| 12/20/2021 | Special Meeting of the CalOptima Board of Directors |

## VIII. REVISION HISTORY

| Action | Date | Policy | Policy Title | Program(s) |
|---|---|---|---|---|
| Effective | 03/01/2017 | MA.6114 | Medication Redeterminations | OneCare<br>OneCare Connect |
| Revised | 04/01/2018 | MA.6114 | Medication Redeterminations | OneCare<br>OneCare Connect |
| Revised | 10/01/2018 | MA.6114 | Medicare Part D Redeterminations | OneCare<br>OneCare Connect |
| Revised | 08/01/2019 | MA.6114 | Medicare Part D Redeterminations | OneCare<br>OneCare Connect |
| Revised | 12/20/2021 | MA.6114 | Medicare Part D Redeterminations | OneCare<br>OneCare Connect |
| Revised | 12/31/2022 | MA.6114 | Medicare Part D Redeterminations | OneCare |
| Revised | 09/01/2023 | MA.6114 | Medicare Part D Redeterminations | OneCare |
| Revised | 11/01/2024 | MA.6114 | Medicare Part D Redeterminations | OneCare |

## IX. GLOSSARY

| Term | Definition |
|---|---|
| Authorized Representative | An individual either appointed by a Member or authorized under State or other applicable law to act on behalf of the Member in filing a grievance, requesting a coverage determination, or in dealing with any level of the appeals process. Unless otherwise stated in Title 42 of the Code of Federal Regulations, Part 423, Subpart M, the representative has all of the rights and responsibilities of a Member in obtaining a coverage determination or in dealing with any of the levels of the appeals process, subject to the rules described in Part 422, Subpart M. |
| Exception | An exception is a type of coverage determination. An exception is a request for coverage for a drug that is not normally on the Formulary (list of covered drugs), or to use the drug without certain rules and limitations. |
| Formulary | The approved list of outpatient medications, medical supplies and devices, and the Utilization Management Protocols as approved by the CalOptima Health Pharmacy & Therapeutics (P&T) Committee for prescribing to Members. |
| Formulary Exception | A formulary exception is a type of coverage determination. A formulary exception is a request to obtain a drug that is not included on CalOptima Health's formulary or to obtain a formulary drug that is subject to a utilization management restriction (e.g., step therapy, prior authorization, quantity limit) which the requestor believes should not apply. |
| Independent Review Entity (IRE) | An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations. |
| Member | A beneficiary enrolled in a CalOptima Health program. |
| Non-Exception | A non-exception is a type of coverage determination. A non-exception is a request for coverage for a drug that is included on CalOptima Health's formulary subject to a utilization management restriction (e.g. step therapy, prior authorization, quantity limit), and the requestor is attempting to satisfy the requirements for coverage. |
| Pharmacy Benefits Manager (PBM) | An entity that provides pharmacy benefit management services, including contracting with a network of pharmacies; establishing payment levels for network pharmacies; negotiating rebate arrangements; developing and managing formularies, preferred drug lists, and prior authorization programs; maintaining patient compliance programs; performing drug utilization review; and operating disease management programs. |
| Prescriber | A healthcare professional who is authorized under State law or other applicable law to write prescriptions. |
| Prescriber Supporting Statement | A statement of medical justification consistent with the requirements set forth in Title 42 of the Code of Federal Regulations, Section 423.578(b)(5).<br><br>An oral or written supporting statement, provided by the Prescriber, that the requested prescription drug is medically necessary to treat the Member's disease or medical condition because—<br>(i) All of the covered Part D drugs on any tier of the formulary for treatment for the same condition would not be as effective for the Member as the non-formulary drug, would have adverse effects for the Member, or both;<br>(ii) The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements—<br>(A) Has been ineffective in the treatment of the Member's disease or medical condition or, based on both sound clinical evidence and medical |

| Term | Definition |
|---|---|
| | and scientific evidence and the known relevant physical or mental characteristics of the Member and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance; or<br>(B) Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the Member; or<br>(iii) The number of doses that is available under a dose restriction for the prescription drug has been ineffective in the treatment of the Member's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical or mental characteristics of the Member and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance. |
| Provider (Part D) | All contracted Providers including physicians, Non-physician Medical Practitioners, ancillary providers, and facilities or institutions who are licensed to furnish Covered Services. |
| Redetermination (Pharmacy) | The first level of the appeal process, which involves a Part D plan sponsor reevaluating an adverse coverage determination, the findings upon which it was based, and any other evidence submitted or obtained. |
| Step Therapy | The Formulary restriction which requires a Member to first try certain drugs to treat a medical condition before the requested medication is covered. |
| Tiering Exception | A tiering exception is a type of coverage determination. A tiering exception is a request to obtain a non-preferred drug in a higher cost-sharing tier at the lower cost-sharing terms applicable to drugs in a lower cost-sharing tier. |
| Utilization Management (UM) | Requirements or limits on coverage. Utilization management may include, but is not limited to, prior authorization, quantity limit, or step therapy restrictions. |