Policy:	MA.6101
Title:	**Medicare Part D Coverage Determination**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 11/22/2024*
Effective Date:	01/01/2006
Revised Date:	11/01/2024
Applicable to:	☐ Medi-Cal ☒ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

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

II. POLICY

A. A Coverage Determination (CD) is any determination (i.e., an approval or denial) made by CalOptima Health with respect to the following:

1. A decision about whether to provide or pay for a drug that the Member believes may be covered by CalOptima Health, including a decision not to pay because:

   a. The drug is not on the plan's Formulary,

   b. The drug is determined not to be Medically Necessary,

   c. The drug is furnished by an out-of-network pharmacy, or

   d. The drug is otherwise excluded under Medicare Part D and/or Medicare Part B.

2. Failure to provide a CD in a timely manner, when a delay would adversely affect the health of the Member;

3. A decision concerning a Tiering Exceptions request under Title 42 of the Code of Federal Regulations, Section 423.578(a);

4. A decision concerning a Formulary Exceptions request under Title 42 of the Code of Federal Regulations, Section 423.578(b);

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

6. A decision whether a Member has, or has not, satisfied a Prior Authorization or other Utilization Management requirement.

B. Who May Request a Coverage Determination (CD)

1. Medicare Part D requests for coverage may be made by a Member, a Member's Prescriber or staff of Prescriber's office acting on the Prescriber's behalf, or a Member's Authorized Representative.

C. With respect to CDs, a Member shall have the following rights:

1. The right to a timely decision;

2. The right to an expedited decision, subject to the provisions of this policy;

3. The right to receive written notice of Tolling;

4. The right to receive detailed written notice of CalOptima Health's decision;

5. The right to request and receive Appeal data from CalOptima Health;

6. The right to receive notice when a request is forwarded to the Independent Review Entity (IRE); and

7. The right to a reconsideration by the IRE.

D. Subject to the provisions of this policy, a Member, a Member's Authorized Representative, or a Member's Prescriber may request a Medicare Part D Exception under the following circumstances:

1. To obtain a non-preferred drug at the more favorable cost-sharing terms applicable to drugs in the preferred tier;

2. The requested drug regimen exceeds CalOptima Health limitations for quantity, refill frequency, duration of therapy, or does not meet Step Therapy restrictions;

3. The requested drug is not on the Formulary; or

4. To waive a Prior Authorization (PA) or other Utilization Management (UM) requirement.

E. A request for a Medicare Part D Formulary Exception will require the Member's Prescriber to provide medical justification or a supporting statement consistent with the requirements set forth in Title 42 of the Code of Federal Regulations, Section 423.578(b)(5).

F. CalOptima Health shall make a CD 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 CD is not made within the defined time frames, CalOptima Health shall auto-forward the request to the IRE.

G. CalOptima Health shall accept CD requests, Exception requests, and Prescriber Supporting Statements in the following formats:

1. Telephone;

2. Mail;

3. Facsimile; and

4. CalOptima Health website.

5. A CD request which involves direct payment or reimbursement to the Member shall only be accepted in writing.

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

H. Subject to the provisions of this Policy, CalOptima Health shall notify a Member, a Member's Authorized Representative, a Member's Prescriber, and a Member's Provider of services of the CD outcome in writing and, in some cases, orally.

I. CalOptima Health's Medical Director shall be responsible for ensuring the clinical accuracy of all Coverage Determinations 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 or other appropriate health care professional with sufficient medical expertise and knowledge of coverage criteria shall review partially or fully adverse Medical Necessity CD decisions. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in the state of California.

2. A pharmacist is considered an appropriate health care professional for purposes of meeting this requirement.

J. 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 CD process, including how to contact CalOptima Health, in the Evidence of Coverage and Member Handbook.

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

III. PROCEDURE

A. When a claim for a potentially Part D drug rejects at the pharmacy point of service (POS) with an electronic notice indicating that the drug is subject to a PA or other UM requirement, the POS pharmacist or other pharmacy personnel shall provide the Member with the standardized Form CMS-10147, Medicare Prescription Drug Coverage and Your Rights.

B. Requesting a Coverage Determination (CD)

1. A Member, a Member's Authorized Representative, a Member's Prescriber, , or a Provider of health care services for the Member, as described in Section II.B of this Policy, may submit a CD request orally, 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 Coverage Determination.

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

2. A CD request for services that have already been furnished:

    a. Shall not be expedited.

    b. Shall be accepted only in written formats when direct payment to the Member is also requested.

C. Requesting an Expedited CD

1. A Member, a Member's Authorized Representative, a Member's Prescriber, or a Provider of health care services for the Member, as described in Section II.B of this policy, may request CalOptima Health to expedite a CD if waiting for a standard CD 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 CD for drugs already furnished to the Member.

3. CalOptima Health shall provide an expedited CD if:

    a. A request to expedite is made or supported by a Prescriber and the Prescriber indicates, either orally 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 CD.

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

    a. Transfer and process the request under the standard CD 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 CD timeframe;

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 CD;

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

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

c. Deliver a written notice, equivalent to the oral notice described in Section III.C.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.

D. 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; and

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.M. of this Policy.

E. 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.M. of this Policy.

F. Requesting a Tiering Exception

1. A request for an Exception to CalOptima Health's tiered cost-sharing structure (Tiering Exception) shall include an oral or written supporting statement from the Prescriber that the drug in the lower cost-sharing tier for treatment of the Member's condition:

    a. Would not be as effective as the requested drug in the higher cost-sharing tier;

    b. Would have adverse effects; or

    c. Both of the above.

2. CalOptima Health is not required to approve a Tiering Exception for a drug in a higher cost-sharing tier at the generic tier cost-sharing level as long as CalOptima Health maintains a separate tier that only includes generic drugs as defined in Title 42 of the Code of Federal Regulations.

3. Under Title 42 of the Code of Federal Regulations, Section 423.578(c)(4)(iii), a Tiering Exception may not be requested for a Non-Formulary drug approved under the Formulary Exception process.

4. CalOptima Health shall grant a Tiering Exception if it determines that the drug in the lower cost-sharing tier for treatment of the Member's condition would not be as effective for the Member as the requested drug and/or would have adverse effects.

G. Requesting a Formulary Exception

1. A request for a Formulary Exception to obtain a Covered Part D Drug that is not included on CalOptima Health's Formulary shall include an oral or written supporting statement from the Prescriber documenting that the requested drug is Medically Necessary to treat the Member's disease or medical condition because all Covered Part D Drugs on any tier of the CalOptima Health Formulary for treatment of the same condition:

    a. Would not be as effective for the Member as the requested drug;

    b. Would have adverse effects for the Member; or

    c. Both of the above.

2. A request for a Formulary Exception to obtain a Covered Part D Drug that is included on CalOptima Health's Formulary and subject to a Step Therapy restriction which the requestor believes should not apply shall include an oral or written supporting statement from the Prescriber documenting that the requested drug is Medically Necessary to treat the Member's disease or medical condition because the prescription drug alternative(s) listed on the Formulary:

    a. Has been ineffective in the treatment of the Member's disease or medical condition; or

    b. Based on sound clinical and medical and scientific evidence, and the known relevant physical or mental characteristics of the Member, and the known characteristics of the drug regimen, it is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

3. A request for a Formulary Exception to obtain a Covered Part D Drug that is included on CalOptima Health's Formulary and subject to a Quantity Limit restriction which the requestor believes should not apply shall include an oral or written supporting statement from the Prescriber documenting that the requested drug is Medically Necessary to treat the Member's disease or medical condition because the number of doses available under a dose restriction (Quantity Limit) for the prescription drug:

    a. Has been ineffective in the treatment of the Member's disease or medical condition; or

    b. Based on sound clinical, medical, and scientific evidence, and the known relevant physical or mental characteristics of the Member, and the known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.

4. A request for a Formulary Exception to obtain a Covered Part D Drug that is included on CalOptima Health's Formulary and subject to a Prior Authorization restriction, which the requestor believes should not apply, shall include an oral or written supporting statement from the Prescriber documenting that:

    a. The requested drug is Medically Necessary to treat the Member's disease or medical condition; and

    b. The Member would suffer adverse effects if he or she were required to satisfy the PA requirement.

5. Under Title 42 of the Code of Federal Regulations, Section 423.578(f), nothing in the regulations or in this Policy should be construed to mean that the Prescriber's Supporting Statement will result in an automatic favorable determination.

6. CalOptima Health may grant a Formulary Exception request if it determines that:

    a. The requested drug is Medically Necessary, based on the physician's or other Prescriber's supporting statement; and

    b. CalOptima Health determines that all Covered Part D Drugs on any tier of the Formulary for treatment of the same condition:

        i. May not be as effective for the Member as the requested drug;

        ii. May have adverse effects for the Member; or

        iii. Both of the above.

7. If CalOptima Health approves a Formulary Exception request to obtain a Covered Part D Drug:

    a. The cost-sharing tier for the approved drug under the Formulary Exceptions process shall be:

        i. Equivalent to the higher cost-sharing tier for all brand name drugs; or

        ii. Equivalent to the lower cost-sharing tier for all generic drugs.

    b. CalOptima Health may choose not to require the Member to resubmit a Formulary Exception request at the beginning of a new plan year. CalOptima Health may auto-extend

Formulary Exception approvals for the following year on a case-by-case basis. If applicable, Members will be notified with an approval letter indicating the new expiration date.

H. Requesting Retrospective Coverage and Payment Reimbursement for a Cash Purchase

1. Any decision made by CalOptima Health about reimbursing a Member for a drug and any decision to reimburse the Member for all or part of a cost-sharing amount is a CD.

2. A request for reimbursement shall be made in writing by one (1) of the individuals described in Section II.B of this Policy.

3. CalOptima Health shall accept a CD for payment reimbursement for a drug.

   a. CalOptima Health's Prescription Drugs Payment Request Form may be used to request reimbursement, but shall not be required.

   b. Copies of prescriptions and receipts may be included with a reimbursement request, but shall not be required.

4. When a reimbursement request must be resolved under the Formulary or Tiering Exceptions process, CalOptima Health shall not toll the timeframe.

5. If CalOptima Health does not have all the information needed to make a decision, reasonable and diligent efforts shall be made to obtain the missing information within the time frames described in Section III.K. of this Policy.

6. CalOptima Health shall make a CD for a drug dispensed as a Cash Purchase at a Non-Participating Pharmacy if:

   a. CalOptima Health cannot reasonably expect the Member to obtain such drugs at a Participating Pharmacy in a timely manner; and

   b. The Member does not access covered drugs at non-Participating Pharmacies on a routine basis.

   c. For purposes of this policy, accessing covered drugs at a Non-Participating Pharmacy on a routine basis shall be construed to mean more than one occurrence per drug per twelve (12)-month period.

7. CalOptima Health shall make a CD for a drug dispensed as a Cash Purchase at a Participating Pharmacy if the circumstances for the Cash Purchase are reasonable, such as:

   a. When the Pharmacy's or CalOptima Health's PBM's system is down;

   b. When a family Member or other person who is filling a prescription on the Member's behalf does not have the Member's benefit card and the Member is not in the Pharmacy's system;

   c. When the Pharmacy or CalOptima Health's PBM mistakenly charge the Member for the drug; or

   d. The prescription was written in connection with a medical emergency or urgent care.

8. If a Member accesses a Covered Part D Drug as a Cash Purchase, the Member may be required to pay the out-of-network differential (that is, the difference between the Non-Participating Pharmacy's usual and customary (U&C) price and CalOptima Health's negotiated rate for such Covered Part D Drug) if the conditions in Section III.H.6 and III.H.7 are not met.

9. The Member shall be required to pay their applicable cost-sharing.

I. Request for CD for Medicare Part B versus Medicare Part D Drugs

1. CalOptima Health shall not consider a drug prescribed to a Member a Covered Part D Drug if payment for such drug is available (or would be available but for the application of a deductible) under Medicare Part A or Medicare Part B for that Member.

2. CalOptima Health relies on the point of service pharmacy to communicate to CalOptima Health the diagnosis provided by the Prescriber to determine whether benefit coverage is required for select covered drugs.

    a. In determining drug coverage under Medicare Part D versus Medicare Part B, CalOptima Health accepts diagnoses documented on the face of the prescription.

    b. Nebulized Inhalation Drugs: If the patient residence code is "3", or "9" indicating the Member is in a Nursing Facility or Intermediate Care Facility, then inhalation drugs used with a nebulizer are Medicare Part D benefits. Inhalation drugs are covered under Medicare Part B when used with a nebulizer in the home.

    c. Oral Anti-Cancer Drugs: Certain oral chemotherapy agents used in cancer treatment are covered by Medicare Part B, as determined by CMS.

    d. Immunosuppressive Drugs: Drugs used in immunosuppressive therapy for a Member who has received a Medicare covered organ transplant are covered under Medicare Part B; else these drugs are likely used for auto-immune conditions and are covered by Medicare Part D benefits.

    e. Drugs for Dialysis-Related Conditions: Drugs used for renal dialysis-related conditions for Member receiving renal dialysis services may have a point of service PA requirement to determine if payment is included in the Medicare Part B bundled payment to a dialysis facility.

    f. In institutional settings, CalOptima Health will also accept diagnoses documented in the medical record by the Prescriber.

    g. The point of service Pharmacy's communication of the diagnosis to CalOptima Health or CalOptima Health's PBM Help Desk may enable the Pharmacy to receive an immediate override for the applicable benefit when the diagnosis supports coverage under Medicare Part B or Medicare Part D.

3. Daily on business days, CalOptima Health shall identify all new pharmacy claim rejections for immunosuppressive drugs for the purpose of making an administrative prospective payment determination.

    a. CalOptima Health shall contact the Member's Pharmacy, the Member's Prescriber, and/or the Member to collect pertinent medical history and diagnosis.

b. Administrative prospective payment determinations shall be made within one (1) business day of identification of the rejected claim.

c. An administrative prospective payment determination shall not be treated as a request for CD.

4. If CalOptima Health determines that the diagnosis is not consistent with Medicare Part D coverage, the request shall be denied as not meeting the definition of a Covered Part D Drug.

a. The Member or the Member's Authorized Representative and the Prescriber shall receive a Notice of Denial of Medicare Prescription Drug Coverage.

b. The Notice of Denial of Medicare Prescription Drug Coverage shall provide an explanation of the conditions of approval as a Medicare Part B Drug.

c. An administrative prospective payment determination of Medicare Part B versus Medicare Part D shall not be subject to CD requirements.

J. Time Frames for Completing Coverage Determinations

1. Standard Prospective Request

a. CalOptima Health shall complete the CD, 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 or, if the request involves a Formulary or Tiering Exception, the date and time CalOptima Health received the Prescriber's Supporting Statement.

2. Expedited Prospective Request

a. CalOptima Health shall complete the CD, 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 twenty-four (24) hours after the date and time CalOptima Health received the request or, if the request involves a Formulary or Tiering Exception, the date and time CalOptima Health received the Prescriber's Supporting Statement.

3. Retrospective Request

a. A retrospective request that does not involve direct payment to the Member shall be resolved under the procedures for standard prospective requests as described in this policy.

b. For a retrospective request involving direct payment to the Member, CalOptima Health shall complete the CD, notify the Member or Member's Authorized Representative and the Prescriber, and effectuate the decision, if applicable, no later than fourteen (14) calendar days after the date and time CalOptima Health received the request.

4. Time Frame Extension

a. Tolling a Medicare Part D Request for a Formulary or Tiering Exception

i. CalOptima Health shall not keep an Exception request open indefinitely if the Prescriber does not submit a supporting statement for the Medical Necessity of the requested drug.

ii. For standard and expedited prospective Exception requests, CalOptima Health shall toll the Exception request for up to seven (7) calendar days and make a CD at the end of the Tolling period with the best available information.

iii. CalOptima Health shall provide written notification to the Member when a Part D Exception request is tolled to obtain a Prescriber Supporting Statement.

iv. Tolling shall not apply for Non-Exception requests.

v. Tolling shall not apply for retrospective payment requests.

5. Auto-forward

a. If CalOptima Health does not make a decision, or fails to provide notice of the decision, in the applicable timeframe, 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 Independent Review Entity (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 Form CMS-10146: Notice of Denial of Medicare Prescription Drug Coverage.

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."

K. 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. However, when 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.

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

4. 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.

5. 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.

6. 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	Twenty-Four (24) Hours	Upon Receipt

7. 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.

L. Refill Too Soon

1. CalOptima Health may grant an override for an early refill as an administrative override and will not require a CD.

   a. A vacation supply of up to ninety (90) calendar days may be granted at a frequency of one (1) override per calendar year per medication.

   b. A replacement supply of lost, stolen, or damaged medication may be granted at a frequency of one (1) override per calendar year per medication for a quantity up to the amount dispensed for the lost, stolen, or damaged medication prescription.

2. On a case-by-case basis, CalOptima Health may initiate a CD for an early refill request which exceeds one (1) request per medication per calendar year.

3. When the early refill request is for a Controlled Medication, CalOptima Health may require a CD and may require additional information on a case-by-case basis, as indicated by the facts and circumstances of each case, such as:

    a. Prescriber approval;

    b. Documentation to support the Member's reason for the request; and/or

    c. A police report.

M. 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 the type of information that should be submitted when seeking a Formulary or Tiering Exception, if applicable;

    c. Information regarding the right to appoint a representative to file an Appeal on the Member's behalf; and

    d. A description of the standard and expedited Redetermination processes and time frames.

3. Written notification is required for all unfavorable decisions (fully or partially unfavorable) pertaining to Medicare Part D.

4. Written notification is required for fully favorable decisions pertaining to Medicare Part D benefits.

5. 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 applicable adjudication timeframe. Oral notifications must satisfy the same requirements as written notifications, as described in Sections III.M.1 and III.M.2. of this Policy.

6. 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 because it is either incorrect, out-of-service, or no person (or no voicemail system) answers, 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 timeframe.

7. When the Member's telephone number and/or mailing address is invalid or missing, CalOptima Health, or its downstream delegated entities, 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.

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

    a. CalOptima Health or its delegated downstream entities 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 or its delegated downstream entity shall attempt to re-send the facsimile and/or outreach to the Prescriber to obtain a working fax number and provide verbal notification of the decision.

9. 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/or CalOptima Health facility mailing procedures.

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

➔ **Requestor** ↓ **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)

N. Documentation and Reporting

1. CalOptima Health's Customer Service Department shall track oral CD 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 CD.

2. CalOptima Health's Pharmacy Management Department shall track written CD requests made by a Member or Member's Authorized Representative in the PBM's Prior Authorization Database.

3. CalOptima Health's Pharmacy Management Department and delegated downstream entities shall track oral and written CD requests made by Prescribers and other Providers in the PBM's Prior Authorization Database.

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

IV. ATTACHMENT(S)

A. Medicare Prescription Drug Coverage and Your Rights (OneCare) IR23_PD003_H5433
B. Notice of Case Status (OneCare) H5433_23PD040
C. Form 1696: Appointment of Representative Form

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. Health and Safety Code, § 1367.01
E. Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Effective July 19, 2024.
F. Social Security Act, §§ 1860D-2, D-43, and 1862
G. Title 42, Code of Federal Regulations (C.F.R.), Part 423, Subpart M

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

Date	Meeting
11/05/2020	Regular Meeting of the CalOptima Board of Directors

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	01/01/2006	MA.6101	Coverage Determination	OneCare
Revised	03/01/2007	MA.6101	Coverage Determination	OneCare
Revised	07/01/2007	MA.6101	Coverage Determination	OneCare
Revised	10/01/2007	MA.6101	Coverage Determination	OneCare
Revised	10/01/2012	MA.6101	Coverage Determination	OneCare
Revised	03/01/2013	MA.6101	Coverage Determination	OneCare
Revised	01/01/2014	MA.6101	Coverage Determination	OneCare
Revised	03/01/2014	MA.6101	Coverage Determination	OneCare
Revised	06/01/2015	MA.6101	Coverage Determination	OneCare OneCare Connect
Revised	03/01/2017	MA.6101	Coverage Determination	OneCare OneCare Connect
Revised	04/01/2018	MA.6101	Coverage Determination	OneCare OneCare Connect

Action	Date	Policy	Policy Title	Program(s)
Revised	10/01/2018	MA.6101	Medicare Part D Coverage Determination	OneCare OneCare Connect
Revised	08/01/2019	MA.6101	Medicare Part D Coverage Determination	OneCare OneCare Connect
Revised	01/01/2021	MA.6101	Medicare Part D Coverage Determination	OneCare OneCare Connect
Revised	11/01/2021	MA.6101	Medicare Part D Coverage Determination	OneCare OneCare Connect
Revised	12/31/2022	MA.6101	Medicare Part D Coverage Determination	OneCare
Revised	09/01/2023	MA.6101	Medicare Part D Coverage Determination	OneCare
Revised	11/01/2024	MA.6101	Medicare Part D Coverage Determination	OneCare

IX. GLOSSARY

Term	Definition
Appeal	As defined at 42 CFR §422.561 and §423.560, the procedures that deal with the review of adverse initial determinations made by the plan on health care services or benefits under Part C or D the enrollee believes he or she is entitled to receive, including a delay in providing, arranging for, or approving the health care services or drug coverage (when a delay would adversely affect the health of the enrollee) or on any amounts the enrollee must pay for a service or drug as defined in 42 CFR §422.566(b) and §423.566(b). These appeal procedures include a plan reconsideration or redetermination (also referred to as a level 1 appeal), a reconsideration by an independent review entity (IRE), adjudication by an Administrative Law Judge (ALJ) or attorney adjudicator, review by the Medicare Appeals Council (Council), and judicial review.
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.
Cash Purchase	A Member's purchase of a covered drug without using their CalOptima Health benefits.
Controlled Medication	A prescription drug that is regulated by the Drug Enforcement Administration (DEA) based on its currently accepted medical use in treatment in the United States, its relative abuse potential, and its likelihood of causing dependence when abused.
Coverage Determination (CD)	Any decision made by CalOptima Health regarding: 1. Receipt of, or payment for, a prescription drug that a Member believes may be covered; 2. A tiering or Formulary Exception request; 3. The amount that the plan sponsor requires a Member to pay for a Part D prescription drug and the Member disagrees with the plan sponsor; 4. A limit on the quantity (or dose) of a requested drug and the Member disagrees with the requirement or dosage limitation; 5. A requirement that a Member try another drug before the plan sponsor will pay for the requested drug and the Member disagrees with the requirement; and 6. A decision whether a Member has, or has not, satisfied a Prior Authorization or other Utilization Management requirement.

Term	Definition
Covered Part D Drug	A Covered Part D Drug includes: 1. A drug that may be dispensed only upon a Prescription, approved by the Food and Drug Administration (FDA), used and sold in the United States, and used for a medically accepted indication as set forth in Section 1927(k)(2)(A) of the Social Security Act; 2. A biological product described in Sections 1927(k)(2)(B)(i) through (iii) of the Social Security Act; 3. Insulin described in Section 1927(k)(2)(C) of the Social Security Act; 4. Medical supplies associated with the delivery of insulin; and 5. A vaccine licensed under Section 351 of the Public Health Service Act and its administration.
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.
Medically Necessary or Medical Necessity	Necessary services to protect life, to prevent significant illness or significant disability, or to alleviate severe pain through the diagnosis or treatment of disease, illness, or injury.
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.
Participating Pharmacy	Any Pharmacy that is credentialed by, and contracted with, the Pharmacy Benefit Manager (PBM) to provide Pharmaceutical Services to Members.
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).

Term	Definition
	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: 1. 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; 2. The prescription drug alternative(s) listed on the Formulary or required to be used in accordance with Step Therapy requirements: a. 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; or 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 3. 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.
Prior Authorization (PA)	The Formulary restriction which requires approval from CalOptima Health before the requested medication is covered.
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.
Quantity Limit (QL)	The Formulary restriction which limits the amount of the requested medication that CalOptima Health will cover.
Redetermination (RD) (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 (ST)	The Formulary restriction which requires an enrollee 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.
Tolling	Extending the timeframe for review of a standard or expedited Formulary or Tiering Exception for a Covered Part D Drug when a Prescriber Supporting Statement has not been received.
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.