Policy:	MA.6115
Title:	**Medicare Part B Organization Determination (OD)**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 01/09/2025*
Effective Date:	11/01/2018
Revised Date:	12/31/2024
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 B.

II. POLICY

A. An Organization Determination (OD) is any determination 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 CalOptima Health'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 B.

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

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

B. Who May Request an Organization Determination (OD)?

1. Medicare Part B requests for coverage may be made by a Member, a Member's Authorized Representative, or any Provider that furnishes, or intends to furnish, services to a Member. A Prescriber or a pharmacist at a dispensing pharmacy shall be considered Providers that furnish, or intend to furnish, services to a Member.

C. With respect to OD, 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 detailed written notice of CalOptima Health's decision and appeal rights; and

4. The right to request and receive appeal data from CalOptima Health.

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 B Exception under the following circumstances:

1. The requested drug regimen exceeds CalOptima Health limitations for quantity, refill frequency, or duration of therapy.

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

E. CalOptima Health shall make an OD 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 CalOptima Health fails to provide the Member with timely notice of an OD, this failure constitutes an adverse OD and may be appealed.

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

1. Telephone;

2. Mail;

3. Facsimile;

4. CalOptima Health website;

5. An OD request which involves direct payment or reimbursement to the Member shall only be accepted in writing; and

6. CalOptima Health shall not require a written request or 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, a Member's Prescriber, and a Member's Provider of services of the OD outcome in writing and, in some cases, verbally.

H. CalOptima Health shall ensure that decisions related to coverage or denial of requested Part B drugs are consistent with the guidelines set forth in this Policy.

1. Criteria and practice guidelines are based on local and national medical evidence. Internal criteria shall be reviewed and approved by the Pharmacy and Therapeutics (P&T) Committee.

2. Criteria and guideline hierarchy includes the following:

    a. CMS National Coverage Determinations (NCD), including NCD with Coverage of Evidence Development (CED);

    b. CMS Local Coverage Determination (LCD) (Noridian Local Contractor for California);

    c. CMS Local Coverage Article (LCA);

    d. CMS Manuals (Medicare Benefit Policy Manual, Medicare National (NCD) Manual, Medicare Claims Processing Manual, etc.);

    e. CMS Local Coverage Determination (LCD) (Non-California) and;

    f. MCG Care Guidelines.

I. CalOptima Health's Medical Director shall be responsible for ensuring the clinical accuracy of all OD 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 shall review partially or fully adverse Medical Necessity OD decisions. The physicians must have a current and unrestricted license to practice within the scope of his or her profession in the state of California.

J. Member Notification

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

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

3. Member notification shall be in accordance with CalOptima Health Policy MA.4002: Cultural and Linguistic Services.

K. Appeals of adverse OD shall be processed by CalOptima Health Grievances and Appeals Resolution Services (GARS) in accordance with CalOptima Health Policies MA.9003: Standard Pre-Service Appeal, MA.9004: Expedited Pre-Service Integrated Appeal, and MA.9015: Standard Integrated Appeals.

III. PROCEDURE

A. A claim for a Part B drug is subject to rejection at the pharmacy point of service (POS) with an electronic notice indicating that the drug is subject to a PA or other UM requirement.

B. Requesting an Organization Determination (OD)

1. A Member, a Member's Authorized Representative, a Member's Prescriber, a Provider that furnishes or intends to furnish services to a Member, or a Provider of health care services for the Member, as described in Section II.B of this policy, may submit an OD 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 an Organization Determination.

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

2. An OD 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 OD

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 an OD if waiting for a standard OD may seriously jeopardize the Member's life, health, or ability to regain maximum function.

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

3. CalOptima Health shall provide an expedited OD 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 OD.

4. If CalOptima Health denies a request by a Member to expedite an OD, CalOptima Health shall proceed as follows:

a. Transfer and process the request under the standard OD 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 OD 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 OD;

iii. Informs the Member of the right to resubmit the request for expedited OD 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 verbal 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. 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.

E. For all decisions, 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.

F. 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 is an OD.

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

3. CalOptima Health shall accept an OD 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. 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.G. of this Policy.

5. CalOptima Health shall make an OD 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.

6. CalOptima Health shall make an OD 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.

7. If a Member accesses a covered Part B Drug as a Cash Purchase, the Member shall not be required to pay the out of network differential.

F. Time Frames for Completing Organization Determinations (OD)

1. Standard Prospective Request

a. CalOptima Health shall complete the OD, 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.

2. Expedited Prospective Request

a. CalOptima Health shall complete the OD, 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.

3. Retrospective Request

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

G. 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 are 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 upon receipt of the OD request.

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.

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 are 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 plan policy upon which the denial decision was based, 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 Reconsideration processes and time frames.

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

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

5. For expedited OD and fully favorable OD, CalOptima Health may make its initial notification verbally so long as it also mails a written follow-up decision within three (3) calendar days of the verbal notification. Verbal notifications must satisfy the same requirements as written notifications, Section III.H.1 and III.H.2. of this Policy.

6. When CalOptima Health has the Member's telephone number on file and relies on it to provide verbal notice, but is unable to reach the Member, its good-faith effort to provide verbal 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 immediately sent to the Member; and

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

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.

I. Documentation and Reporting

1. CalOptima Health's Customer Service Department shall track verbal OD 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 an OD.

2. CalOptima Health's Pharmacy Management Department shall track written OD 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 verbal and written OD 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 OD 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. Prescription Drugs Payment Request Form (OneCare) H5433_25IRPD002_C
C. Coverage Decision Letter CMS Form 10716 (OneCare) H5433_25UM001_C
D. Appeal Decision Letter
E. Form 1696: Appointment of Representative Form
F. Notice of Rights to an Expedited Grievance (OneCare) H5433_21GA003_C

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 GA.7107: Mail Collection and Delivery
D. CalOptima Health Policy MA.2001: Marketing Material Standards
E. CalOptima Health Policy MA.4002: Cultural and Linguistic Services
F. CalOptima Health Policy MA.9003: Standard Pre-Service Appeal
G. CalOptima Health Policy MA.9004: Expedited Pre-Service Integrated Appeal
H. CalOptima Health Policy MA.9015: Standard Integrated Appeals
I. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Effective July 19, 2024

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

None to Date

VIII. REVISION HISTORY

Action	Date	Policy	Policy Title	Program(s)
Effective	11/01/2018	MA.6115	Medicare Part B Organization Determinations	OneCare OneCare Connect
Revised	11/01/2019	MA.6115	Medicare Part B Organization Determinations	OneCare OneCare Connect
Revised	01/01/2020	MA.6115	Medicare Part B Organization Determinations	OneCare OneCare Connect
Revised	10/01/2021	MA.6115	Medicare Part B Organization Determinations	OneCare OneCare Connect
Revised	12/31/2022	MA.6115	Medicare Part B Organization Determinations	OneCare
Revised	09/01/2023	MA.6115	Medicare Part B Organization Determination (OD)	OneCare
Revised	11/01/2024	MA.6115	Medicare Part B Organization Determination (OD)	OneCare
Revised	12/31/2024	MA.6115	Medicare Part B Organization Determination (OD)	OneCare

IX. GLOSSARY

Term	Definition
Authorized Representative	An individual 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 beneficiary resides may allow, in order to execute an enrollment or disenrollment request; 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 beneficiary in this capacity (see §40.2.1). Form CMS-1696 may not be used to appoint an authorized representative for the purposes of enrollment and disenrollment. This form is solely for use in the claims adjudication or claim appeals process, and does not provide broad legal authority to make another individual's healthcare decisions.
Cash Purchase	A Member's purchase of a covered drug without using their CalOptima Health benefits.
Centers for Medicare & Medicaid Services (CMS)	The federal agency under the United States Department of Health and Human Services responsible for administering the Medicare and Medicaid programs.
Formulary	The approved list of outpatient medications, medical supplies and devices, and the Utilization and Contingent Therapy Protocols as approved by the CalOptima Health Pharmacy & Therapeutics (P&T) Committee for prescribing to Members without the need for Prior Authorization.
Independent Review Entity (IRE)	An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.
Medically Necessary	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.
Medicare Part B	Medicare Part B (Medical Insurance) helps cover doctors' services and outpatient care. It also covers some other medical services that Part A doesn't cover, such as some of the services of physical and occupational therapists, and some home health care. Part B helps pay for these covered services and supplies when they are medically necessary.
Member	A beneficiary enrolled in a CalOptima Health program.
Organization Determination (OD)	Any determination made by CalOptima Health, or its delegated entity with respect the following: 1. Payment for temporarily out-of-area renal dialysis services, emergency services, post-stabilization care, or urgently needed services; 2. Payment for any other health services furnished by a Provider that the Member believes: a. Are covered under Medicare; or b. If not covered under Medicare, should have been furnished, arranged for, or reimbursed by CalOptima Health. 3. Refusal to authorize, provide or pay for services, in whole or in part, including the type or level of services, which the Member believes should be furnished or arranged by CalOptima Health; 4. Reduction or premature discontinuation, of a previously authorized ongoing course of treatment; or 5. Failure to approve, furnish, arrange for, or provide payment for health care services in a timely manner, or to provide timely notice of an adverse determination, such that a delay would adversely affect the health of the Member.

Term	Definition
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	For the purpose of this policy, a prescriber is a healthcare professional who is authorized under State law or other applicable law to write prescriptions, a physician, or staff of physician's office acting on physician's behalf.
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). A verbal 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.
Prior Authorization (PA) (Pharmacy)	The Formulary restriction which requires approval from CalOptima Health before the requested medication is covered.
Provider	Any Medicare provider (e.g., hospital, skilled nursing facility, home health agency, outpatient physical therapy, comprehensive outpatient rehabilitation facility, end-stage renal disease facility, hospice, physician, non-physician provider, laboratory, supplier, etc.) providing Covered Services under Medicare Part B. Any organization, institution, or individual that provides Covered Services to Medicare members. Physicians, ambulatory surgical centers, and outpatient clinics are some of the providers of Covered Services under Medicare Part B.
Quantity Limit (QL)	The Formulary restriction which limits the amount of the requested medication that CalOptima Health will cover.
Reconsideration	Under Part C, the first level in the appeals process which involves a review of an adverse organization determination by CalOptima Health, the evidence and findings upon which it was based, and any other evidence submitted by a party to the organization determination, CalOptima Health or CMS. Under Part D, the second level in the appeals process which involves a review of an adverse coverage determination by an independent review entity (IRE), the evidence and findings upon which it was based, and any other evidence the enrollee submits, or the IRE obtains. As used in this guidance, the term may refer to the first level in the Part C appeals process in which CalOptima Health reviews an adverse Part C organization determination or the second level of appeal in both the Part C and Part D appeals process in which an independent review entity reviews an adverse plan decision.
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.