Policy:	MA.6110
Title:	**Transition Process**
Department:	Medical Management
Section:	Pharmacy Management
CEO Approval:	*/s/ Michael Hunn 12/16/2024*
Effective Date:	03/01/2007
Revised Date:	12/01/2024
Applicable to:	☐ Medi-Cal ☒ OneCare ☐ PACE ☐ Administrative

I. PURPOSE

This policy describes CalOptima Health's transition process for Members in a transition period in order to obtain a temporary supply of non-Formulary Part D drugs, or Formulary drugs that have Prior Authorization or other Utilization Management (UM) restriction.

II. POLICY

A. CalOptima Health's transition process shall provide Members who qualify, a one-time, temporary supply of a non-Formulary Part D drug, or Formulary drug that requires a Prior Authorization, or Step Therapy, to accommodate an immediate need and to allow sufficient time to work with the prescriber to use a Formulary alternative, or complete an exceptions request.

B. CalOptima Health's transition process shall apply to:

1. A new Member joining CalOptima Health following the Annual Election Period or Special Election Period;

2. A new Member joining CalOptima Health from other coverage during the current year;

3. An individual who switches to CalOptima Health from another health plan after the start of the contract year;

4. A Member residing in a Long-Term Care (LTC) facility;

5. A Member changing treatment settings due to changes in level of care; and

6. A continuing Member affected by Formulary changes from one (1) contract year to the next.

C. CalOptima Health's transition process requirements shall be applicable to non-Formulary drugs that are:

1. Part D drugs not on the CalOptima Health Formulary;

2. Part D drugs previously approved for coverage under an exception once the exception expires; and

3. Part D drugs on the CalOptima Health Formulary but for which usage is subject to UM rules, such as Prior Authorization or Step Therapy restrictions, or that have an approved quantity limit lower than the Member's current dose.

D. To assist a Member during the transition process, CalOptima Health may:

1. Analyze claims data to identify Members who require information about their transition supply;

2. Provide a Member with the necessary information to enable the Member to switch to a Formulary drug, or to pursue necessary Prior Authorizations, or Formulary exceptions; or

3. Extend the transition period if CalOptima Health has not processed the Member's exception request or Appeal by the end of the minimum transition period.

E. CalOptima Health enforces the following drug UM edits during a transition period to:

1. Determine Part A or B vs. Part D coverage;

2. Prevent coverage of non-Part D drugs (i.e., excluded drugs); and

3. Promote safe utilization of a Part D drug (e.g., quantity limits based on the U.S. Food and Drug Administration (FDA) maximum recommended daily dose, or early refill edits).

F. CalOptima Health may deny access to quantities or doses for safety reasons during the transition process. Prior to implementing a denial, CalOptima Health shall ensure and track that:

1. An initial transition supply has been provided up to the maximum allowable dose; and

2. CalOptima Health has assisted the Member and the prescriber in filling a therapeutically appropriate Formulary alternative, or has processed an exception request.

G. CalOptima Health's Pharmacy and Therapeutics (P&T) Committee shall review and provide recommendations regarding the procedures for medical review of non-Formulary Part D drug requests.

H. CalOptima Health shall ensure that a new Member is able to leave a CalOptima Health network pharmacy with a temporary supply of non-Formulary Part D drugs without unnecessary delays.

III. PROCEDURE

A. Implementation Statement

1. The claims adjudication system has capabilities that allow CalOptima Health to provide a temporary supply of non-Formulary Part D drugs in order to accommodate the immediate needs of a Member, as well as to allow CalOptima Health and/or the Member sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

2. CalOptima Health utilizes the current NCPDP Telecommunication Standard to provide POS messaging. Pharmacy messages are modified based on industry standards.

3. CalOptima Health shall only apply the following UM edits during transition at Point-of-Sale (POS). Step Therapy and Prior Authorization edits must be resolved at POS.

    a. Edits to determine Part A or B versus Part D coverage;

    b. Edits to prevent coverage of non-Part D drugs;

    c. Edits to help determine Part D coverage (i.e., Member level PAs); and

    d. Edits to promote safe utilization of a Part D drug.

4. As outlined in Title 42, Section 423.153(b) of the Code of Federal Regulations, CalOptima Health has implemented POS Prior Authorization edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) and Cialis drugs as an example).

5. CalOptima Health shall provide refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.

6. During the Member's transition period, all edits (with the exception of those outlined in Section III.J.1-4) associated with non-Formulary drugs are automatically overridden at the POS. Pharmacies can also contact the Pharmacy Help Desk directly for immediate assistance with POS overrides. CalOptima Health can also accommodate overrides at POS for emergency fills as described in Sections III.F and III.H.

B. Temporary One-Time Fills

1. CalOptima Health shall provide a one-time, temporary supply ("transition fill") of non-Formulary Part D drugs or Part D drugs on the CalOptima Health Formulary that have Step Therapy restrictions or require a PA, and are not medically contraindicated, to accommodate the immediate needs of a Member, as described in Section II.B of this Policy.

2. In the outpatient setting, CalOptima Health shall provide at least thirty (30) calendar days of medication anytime during the first ninety (90) calendar days of a Member's enrollment in OneCare, beginning on the Member's first effective date of coverage, for a one-time, temporary supply of drugs, in accordance with this Policy, unless the prescriber writes the prescription for less than thirty (30) calendar days. CalOptima Health will allow multiple fills to provide up to a total of thirty (30) calendar days of medication.

C. CalOptima Health shall charge cost sharing for a temporary supply of drugs provided under the transition process such that the following conditions are met:

1. Cost-sharing for transition supplies for low-income subsidy (LIS) Members shall not exceed the statutory maximum copayment amount.

2. Cost-sharing for transition supplies for non-LIS Members shall be:

    a. The same cost sharing for non-Formulary drugs provided during the transition that would apply for non-Formulary drugs approved through a Formulary exception.

b. The same cost sharing for Formulary drugs subject to UM edits provided during the transition that would apply if the UM criteria are met.

D. Transition Timeframes

1. CalOptima Health shall provide a temporary supply of non-Formulary Part D drugs, in accordance with this policy, at any time during the Member's first ninety (90) calendar days of enrollment in CalOptima Health. The ninety (90) calendar days timeframe applies to retail and home infusion (outpatient) pharmacies, and long-term care (LTC) pharmacies.

2. For a Member who joins CalOptima Health at any time during the contract year, this requirement shall apply at the beginning from the Member's first effective date of coverage, and not only to the first ninety (90) calendar days of the contract year.

3. During the transition timeframe, CalOptima Health shall provide a temporary transition fill of non-Formulary Part D drugs or Formulary drugs with Prior Authorization or Step Therapy edits if the Member is in the following setting:

   a. In an outpatient setting, CalOptima Health shall offer a one-time, temporary supply for at least thirty (30) calendar days of medication, unless the prescription is written by a prescriber for less than thirty (30) calendar days.

   b. In a long-term care (LTC) setting, CalOptima Health shall offer a temporary supply of at least ninety-one (91) calendar days (and up to at least ninety-eight (98) calendar days, consistent with the dispensing increment), unless the prescription is written for less, with multiple refills during a ninety (90) calendar day transition period.

   c. A transition extension may be granted on a case-by-case basis, if a Member's exception request or appeal for a non-Formulary Part D drug has not been processed by the end of the Transition Period and until a transition has been made (through a switch to an appropriate Formulary drug or a decision on an exception request).

   d. In the event CalOptima Health does not make a decision timely or does not forward the Member's exception request/case file to the Independent Review Entity (IRE) within the appropriate time frame, CalOptima Health shall provide a temporary supply of the requested drug until the case is resolved by CalOptima Health, or the IRE issues a reconsideration decision.

4. When a distinction cannot be made at the POS between a brand-new prescription for a non-Formulary drug and an ongoing prescription for a non-Formulary drug, CalOptima Health shall provide the Member with a transition fill.

E. Transition Across Contract Years

1. These transition requirements apply to drugs that are removed from CalOptima Health's Formulary from one contract year to the next, as well as to Formulary drugs that remain on Formulary but to which a new Prior Authorization or Step Therapy restriction is added from one contract year to the next:

   a. If a Member enrolls in CalOptima Health with an effective date of coverage of either November 1 or December 1, and needs a transition supply, CalOptima Health shall extend the transition process across contract years.

b. CalOptima Health shall send an Annual Notice of Change (ANOC) and abridged Formulary, by the CMS designated date as required for the annual election or open enrollment period to notify the Member of any Formulary or benefit changes.

2. For current Members whose drugs will be affected by negative Formulary changes in the upcoming year (no longer on CalOptima Health's Formulary, or remain on the Formulary but to which new UM restrictions are applied), CalOptima Health shall effectuate a meaningful transition by either:

   a. Providing a transition process consistent with the transition process required for new Members at the start of the new contract year; or

   b. Effectuating a transition prior to the start of the new contract year. This includes prospectively transitioning current Members to therapeutically equivalent Formulary alternatives, and adjudicating any requests for exceptions to the new Formulary prior to the start of the contract year.

F. CalOptima Health shall cover an emergency supply of non-Formulary Part D drugs for LTC facility residents as part of their transition process. If the Member in an LTC setting is outside his or her ninety (90) calendar day Transition Period, CalOptima Health shall provide an emergency supply of non-Formulary Part D drugs while an exception or Prior Authorization is requested. These emergency supplies must be for at least thirty-one (31) calendar days of medication, unless the prescription is written by a prescriber for less than thirty-one (31) calendar days.

G. Level of Care Changes

1. Other circumstances may arise involving level of care changes in which a Member is changing from one (1) treatment setting to another, such as:

   a. When a Member enters an LTC facility from a hospital and is accompanied by a discharge list of medications from the hospital Formulary with very short-term planning taken into account;

   b. When a Member is discharged from a hospital to a home;

   c. When a Member ends their skilled nursing facility and needs to revert to the CalOptima Health Formulary;

   d. When a Member gives up hospice status to revert to standard Medicare benefits;

   e. When a Member ends an LTC facility stay and returns to the community; and/or

   f. When a Member is discharged from a psychiatric hospital with a drug regimen that is highly customized.

2. For these unplanned transitions, CalOptima Health shall make Coverage Determinations and Redeterminations as expeditiously as the Member's health condition requires.

3. CalOptima Health shall provide transition supplies to a Member with level of care changes from one (1) treatment setting to another.

4. CalOptima Health shall allow a Member to access a refill upon admission or discharge from a LTC facility in connection with early refill edits.

H. Transition Process in the LTC Setting

1. CalOptima Health shall make every effort to ensure that LTC pharmacies in the CalOptima Health pharmacy network have relationships with LTC facilities, and work with those facilities prior to the effective date of coverage to ensure a seamless transition of a facility's resident.

2. CalOptima Health shall provide at least a ninety-one (91) calendar day transition supply of drugs, and up to a ninety-eight (98) calendar day supply, consistent with the dispensing increment of fourteen (14) calendar days for a brand drug, and thirty-one (31) calendar days for a generic drug, with multiple refills, as necessary, during the entire length of the ninety (90) calendar day transition period for a new Member in a LTC facility, unless the prescriber writes the prescription for a lesser amount.

3. CalOptima Health shall provide a thirty-one (31) calendar day emergency supply of non-Formulary Part D drugs for a Member outside their ninety (90) calendar day transition period while CalOptima Health processes an exception request or Prior Authorization, unless the prescriber writes the prescription for less than thirty-one (31) calendar days.

4. CalOptima Health shall provide up to a thirty-one (31) calendar day emergency supply of non-Formulary drugs while CalOptima Health processes an exception for a Member entering a LTC setting from another care setting.

I. Monitoring of Transition Fills

1. CalOptima Health will monitor daily rejections to determine if prescription can be filled as a transition. If a transition fill is determined to be appropriate, CalOptima Health will outreach to the pharmacy to provide assistance in transition fill processing and ensure that a transition notice is sent to the Member.

J. Edits for Transition Supplies

1. To promote safe utilization, CalOptima Health shall use quantity limits based on the U.S. Food and Drug Administration (FDA) maximum recommended daily dose or early refill edits as approved by the P&T Committee.

2. CalOptima Health may use UM edits during the transition period for drugs that require Part A or B vs. Part D determination.

3. CalOptima Health will apply edits to prevent coverage of non-Part D drugs during the transition period.

4. CalOptima Health shall provide refills to meet the transition supply requirement for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.

5. During the Member's transition period, all edits (with the exception of those outlined in Section III.J.1-4) associated with non-Formulary drugs and Formulary drugs with Prior Authorization and Step Therapy restrictions are automatically overridden at the POS. Pharmacies can also contact the Pharmacy Help Desk directly for immediate assistance with POS overrides.

K. Transition Notices

1. CalOptima Health shall send a written notice regarding the transition process to a Member who received a transition fill, via United States Postal Service (USPS) mail, within three (3) business

days of a temporary fill, in accordance with the Centers for Medicare & Medicaid Services (CMS) requirement. If the Member receives a transition supply in multiple fills, CalOptima Health shall send notice with the first transition fill only. This applies to long-term care residents dispensed multiple supplies in increments of fourteen (14) calendar days, or less.

2. CalOptima Health will make reasonable efforts to notify the prescriber of the transition supply for affected Members. The prescriber's transition notice will be sent via USPS mail.

3. The CalOptima Health transition notice shall include the following:

   a. An explanation that the transition fill is temporary, and that the Member may not refill the supply unless CalOptima Health approves a Formulary exception or provides a favorable Coverage Determination for the UM edits;

   b. Instructions for the Member to work with CalOptima Health and the Member's prescriber to satisfy UM requirements or to identify appropriate therapeutic alternatives that are on the CalOptima Health Formulary;

   c. An explanation of the Member's right to request a Formulary exception, the time frames for CalOptima Health to process the exception request, and the Member's right to request an Appeal if CalOptima Health issues an unfavorable decision; and

   d. A description of the procedures for requesting a Formulary exception.

4. Pursuant to CMS marketing guidelines, CalOptima Health shall use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a forty-five (45) day review.

5. CalOptima Health shall make Prior Authorization or exception request forms available, upon request, to both Members and prescribers by:

   a. U.S.P.S. mail;

   b. Facsimile;

   c. Email; or

   d. CalOptima Health Website.

6. CalOptima Health and its trading partners, including pharmacies, shall adopt, per CMS' requirement, a structured payment coding in the message field of billing transaction responses indicating that a particular fill is a transition supply. The process is consistent with the current National Council for Prescription Drug Programs (NCPDP) telecommunication standards, for use and implementation, until such time as such messaging is superseded by a new HIPAA-approved standard with appropriate coding.

L. Public Notice of Transition Process

1. CalOptima Health shall make general information about the transition process available to a Member in a manner similar to information provided on formularies and benefit design.

2. CalOptima Health shall make available CalOptima Health's transition process information via a required link from the Medicare Prescription Drug Plan Finder to the CalOptima Health Website using CMS' model submission forms.

3. Pursuant to CMS marketing guidelines, CalOptima Health shall include transition process information in the pre- and post-enrollment materials, as appropriate.

M. Medical review of non-Formulary drug requests is performed in accordance with CalOptima Health Policy MA.6101: Medicare Part D Coverage Determination. When appropriate, therapeutically appropriate Formulary alternatives are suggested, failing an affirmative medical necessity determination.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCE(S)

A. CalOptima Health Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
B. CalOptima Health Policy MA.6101: Medicare Part D Coverage Determination
C. HPMS Memorandum: Part D Transition Monitoring Program. Dated 12-29-16
D. Medicare Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary Requirements. Rev. 18, 01-15-16
E. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Effective July 19, 2024
F. Title 42, Code of Federal Regulations, §423.120 b(3)(iii)(B)
G. 76, Federal Register, Section 21572, Apr. 15, 2011

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	03/01/2007	MA.6110	Transition Process	OneCare
Revised	08/01/2008	MA.6110	Transition Process	OneCare
Revised	01/01/2013	MA.6110	Transition Process	OneCare
Revised	06/01/2013	MA.6110	Transition Process	OneCare
Revised	06/01/2015	MA.6110	Transition Process	OneCare OneCare Connect
Revised	11/01/2016	MA.6110	Transition Process	OneCare OneCare Connect
Revised	11/01/2017	MA.6110	Transition Process	OneCare OneCare Connect
Revised	10/01/2018	MA.6110	Transition Process	OneCare OneCare Connect
Revised	08/01/2019	MA.6110	Transition Process	OneCare OneCare Connect
Revised	10/01/2021	MA.6110	Transition Process	OneCare OneCare Connect
Revised	12/31/2022	MA.6110	Transition Process	OneCare

Action	Date	Policy	Policy Title	Program(s)
Revised	09/01/2023	MA.6110	Transition Process	OneCare
Revised	12/01/2024	MA.6110	Transition Process	OneCare

IX. GLOSSARY

Term	Definition
Annual Election Period	An Open Election Period that takes place from October 15 through December 7.
Coverage Determination	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.
Coverage Determination Exception	A Coverage Determination related to: 1. CalOptima Health's tiered cost-sharing structure; or 2. A Part D Covered Drug that is not on the CalOptima Health's Formulary.
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 the Centers for Medicare & Medicaid Services (CMS) to review denial of Coverage Determinations.
Member	For the purposes of this policy, an enrollee-beneficiary of the OneCare Program.
Prior Authorization (Pharmacy)	The Formulary restriction which requires approval from CalOptima Health before the requested medication is covered.
Redetermination	For the purposes of this policy, 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.
Special Election Period	Election Period provided to individuals in situations where; 1. The individual has made a change in residence outside of the service area or continuation area or has experienced another change in circumstances as determined by Centers for Medicare & Medicaid Services (CMS) (other than termination for non-payment of premiums or disruptive behavior) that causes the individual to no longer be eligible to elect the Medicare Advantage plan; 2. CMS or the organization has terminated the Medicare Advantage organization's contract for the Medicare Advantage plan in the area in which the individual resides, or the organization has notified the individual of the impending termination of the plan or the impending discontinuation of the plan in the area in which the individual resides; 3. The individual demonstrates that the Medicare Advantage organization offering the Medicare Advantage plan substantially violated a material provision of its contract under Medicare Advantage in relation to the

Term	Definition
	individual, or the Medicare Advantage organization (or its agent) materially misrepresented the plan when marketing the plan; 4. The individual is entitled to Medicare Part A and Part B and receives any type of assistance from Medi-Cal; or 5. The individual meets such other exceptional conditions as CMS may provide.
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.
Transition Period/Timeframe	A Member's Transition Period/Timeframe begins with the date of each enrollment. Even if a Member leaves CalOptima Health and then re-enrolls the following month, the Transition Period/Timeframe shall begin with each enrollment for ninety (90) days.