



Medication Transition Policy

New members in our plan may be taking drugs that are not on our formulary, or that are subject to certain restrictions, such as prior authorization or step therapy. Members should talk to their doctors to decide if they should switch to an appropriate drug that we cover or request a formulary exception (which is a type of coverage determination) in order to get coverage for the drug .

While these new members might talk to their doctors to determine the right course of action, OneCare may cover the non-formulary drug in certain cases during the first 90 days of new membership. For each of the drugs that is not on our formulary or that have coverage restrictions or limits, we will cover a temporary 30 day supply (unless the prescription is written for fewer days) when the new member goes to a network pharmacy (and the drug is otherwise a “Part D drug). After the first 30 day supply, we will not pay for these drugs, even if the new member has been a member of OneCare less than 90 days.

If the new member is a resident of a long-term care facility, we will cover at least a 91day transition supply of drugs, and up to a 98-day supply, consistent with the dispensing increment (unless the member has a prescription written for fewer days). We will cover more than one refill of these drugs for the first 90 days for a new member of our plan. If a new member needs a drug that is not on our formulary or subject to other restrictions, such as step therapy or dosage limits, but the new member is past the first 90 days of new membership in our plan, we will cover a 31 day emergency supply of that drug (unless the prescription is for fewer days) while the new member pursues a formulary exception.

Please note that our transition policy applies only to those drugs that are “Part D drugs” and that are purchased at a network pharmacy. The transition policy cannot be used to purchase a non-covered drug or drug out-of-network. In some cases, we will contact the member if the member is taking a drug that is not on our formulary. We can give the member the names of covered drugs that also are used to treat the member’s condition so the member can ask his or her doctor if any of these drugs are an option for treatment.

For questions about our transition policy, please call Customer Service at **1-877-412-2734**, TDD/TTY users can call **1-800-735-2929**. We take calls 24 hours a day, 7 days a week.



Policy: MA.6110
Title: **Transition Process**
Department: Medical Affairs
Section: Pharmacy Management

CEO Approval: /s/ Michael Schrader 08/27/2019

Effective Date: 03/01/2007

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Applicable to: OneCare
 OneCare Connect

I. PURPOSE

This policy describes CalOptima'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 restriction.

II. POLICY

- A. CalOptima'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's transition process shall apply to:
1. A new **Member** joining CalOptima following the **Annual Election Period** or **Special Election Period**;
 2. A new **Member** joining CalOptima from other coverage during the current year;
 3. An individual who switches to CalOptima 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's transition process requirements shall be applicable to non-formulary drugs that are:
1. Part D drugs not on the CalOptima **Formulary**; and
 2. Part D drugs previously approved for coverage under an **Exception** once the **Exception** expires; and
 3. Part D drugs on the CalOptima **Formulary** but for which usage is subject to utilization management (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 may:
1. Analyze claims data to identify **Members** who require information about their transition supply; or
 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 has not processed the **Member's Exception** request or **Appeal** by the end of the minimum transition period.
- E. CalOptima enforces the following drug utilization management 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 may deny access to quantities or doses for safety reasons during the transition process. Prior to implementing a denial, CalOptima shall ensure and track that:
1. An initial transition supply has been provided up to the maximum allowable dose; and
 2. CalOptima has assisted the **Member** and the prescriber in filling a therapeutically appropriate formulary alternative, or has processed an **Exception** request.
- G. CalOptima'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 shall ensure that a new **Member** is able to leave a CalOptima 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 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 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 utilizes the current NCPDP Telecommunication Standard to provide POS messaging. Pharmacy messages are modified based on industry standards.
3. CalOptima shall only apply the following utilization management edits during transition at point-of-sale. Step Therapy and Prior Authorization edits must be resolved at point-of-sale (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 has implemented Point-of-Sale (POS) PA 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 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 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 shall provide a one-time, temporary supply ("transition fill") of non-formulary Part D drugs or Part D drugs on the CalOptima **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 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 or OneCare Connect, 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 will allow multiple fills to provide up to a total of thirty (30) calendar days of medication.

C. CalOptima 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 utilization management edits provided during the transition that would apply if the utilization management criteria are met.

D. Transition Timeframes

1. CalOptima 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. The ninety (90) calendar day time frame applies to retail and home infusion (outpatient) pharmacies, and long-term care (LTC) pharmacies.
2. For a **Member** who joins CalOptima 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 shall provide a temporary transition fill of non-formulary Part D drugs or formulary drugs with PA or Step Therapy edits if the Member is in the following setting:
 - a. In an outpatient setting, CalOptima 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. For Members in OneCare Connect, transitions are allowed for non-Part D drugs that are part of the additional drugs under demonstration (ADD) benefit.
 - c. In a long-term care (LTC) setting, CalOptima 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.
 - d. 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).
 - e. In the event CalOptima 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 shall provide a temporary supply of the requested drug until the case is resolved by CalOptima 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 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's **Formulary** from one contract year to the next, as well as to formulary drugs that remain on **Formulary** but to which a new **PA** or **Step Therapy** restriction is added from one contract year to the next:
 - a. If a **Member** enrolls in CalOptima with an effective date of coverage of either November 1 or December 1, and needs a transition supply, CalOptima shall extend the transition process across contract years.
 - b. CalOptima 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's formulary, or remain on the formulary but to which new utilization management restrictions are applied), CalOptima 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 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 shall provide an emergency supply of non-formulary Part D drugs while an **Exception** or **PA** 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 **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 shall make **Coverage Determinations** and **Redeterminations** as expeditiously as the **Member's** health condition requires.
3. CalOptima shall provide transition supplies to a **Member** with level of care changes from one (1) treatment setting to another.
4. CalOptima 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 shall make every effort to ensure that LTC pharmacies in the CalOptima 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 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 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 processes an **Exception** request or **Prior Authorization**, unless the prescriber writes the prescription for less than thirty-one (31) calendar days.
4. CalOptima shall provide up to a thirty-one (31) calendar day emergency supply of non-formulary drugs while CalOptima processes an **Exception** for a **Member** entering a LTC setting from another care setting.

I. Monitoring of Transition Fills

1. CalOptima will monitor daily rejections to determine if prescription can be filled as a transition. If a transition fill is determined to be appropriate, CalOptima 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 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 may use utilization management edits during the transition period for drugs that require Part A or B vs. Part D determination.
3. CalOptima will apply edits to prevent coverage of non-Part D drugs during the transition period.
4. CalOptima 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 **PA** and **Step Therapy** restrictions are automatically overridden at the POS. Pharmacies can also contact the Pharmacy Help Desk directly for immediate assistance with point of sale (POS) overrides.

K. Transition Notices

1. CalOptima shall send a written notice regarding the transition process to a **Member** who received a transition fill, via U.S. P.S. 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 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 will make reasonable efforts to notify the prescriber of the transition supply for affected **Members**. The prescriber's transition notice will be sent via United States Postal Service (USPS) mail.
3. The CalOptima 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 approves a **Formulary Exception** or provides a favorable **Coverage Determination** for the UM edits;
 - b. Instructions for the **Member** to work with CalOptima and the **Member's** prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the CalOptima **Formulary**;
 - c. An explanation of the **Member's** right to request a formulary **Exception**, the time frames for CalOptima to process the **Exception** request, and the **Member's** right to request an **Appeal** if CalOptima issues an unfavorable decision; and
 - d. A description of the procedures for requesting a formulary **Exception**.
4. Pursuant to CMS marketing guidelines, CalOptima 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 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 Website.
6. CalOptima 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 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 shall make available CalOptima’s transition process information via a required link from the Medicare Prescription Drug Plan Finder to the CalOptima Website using CMS’ model submission forms.
3. Pursuant to CMS marketing guidelines, CalOptima 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 Policy MA.6101 Coverage Determination. When appropriate, therapeutically appropriate formulary alternatives are suggested, failing an affirmative medical necessity determination.

IV. ATTACHMENT(S)

Not Applicable

V. REFERENCES

- A. 76, Federal Register, Section 21572, Apr. 15, 2011
- B. CalOptima Contract with the Centers for Medicare & Medicaid Services (CMS) for Medicare Advantage
- C. CalOptima Policy MA.6101: Coverage Determination
- D. CalOptima Three-Way Contract with the Centers for Medicare & Medicaid Services (CMS) and the Department of Health Care Services (DHCS) for Cal MediConnect
- E. HPMS memorandum dated 12-29-16: Part D Transition Monitoring Program
- F. Medicare Prescription Drug Benefit Manual, Chapter 6: Part D Drugs and Formulary Requirements. Rev. 18, 01-15-16
- G. Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance, Released February 2019
- H. Title 42, Code of Federal Regulations, §423.120 b(3)(iii)(B)

VI. REGULATORY AGENCY APPROVAL(S)

None to Date

VII. BOARD ACTION(S)

None to Date

VIII. REVISION HISTORY

Version	Date	Policy Number	Policy Title	Line(s) of Business
Effective	03/01/2007	MA.6110	Transition Process	OneCare
Revised	08/01/2008	MA.6110	Transition Process	OneCare
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Revised	06/01/2015	MA.6110	Transition Process	OneCare OneCare Connect
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IX. GLOSSARY

Term	Definition
Annual Election Period	An Open Election Period that takes place from October 15 through December 7
Coverage Determination	Any decision, or failure to decide in a timely manner, made by or on behalf of a Part D plan sponsor regarding payment or benefits to which an enrollee believes he or she is entitled.
Coverage Determination Exception	A Coverage Determination related to: <ol style="list-style-type: none"> 1. CalOptima’s tiered cost-sharing structure; or 2. A Part D Covered Drug that is not on the CalOptima’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 Pharmacy & Therapeutics (P&T) Committee for prescribing to Members without the need for Prior Authorization.
Member	For the purposes of this policy, an enrollee-beneficiary of the OneCare or OneCare Connect Program.
Prior Authorization (Pharmacy)	The formulary restriction which requires approval from CalOptima 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; <ol style="list-style-type: none"> 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 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 and then re-enrolls the following month, the Transition Period/Timeframe shall begin with each enrollment for ninety (90) days.

Term	Definition
Independent Review Entity (IRE)	An independent entity contracted by CMS to review Part D plan sponsor denials of coverage determinations.