

Medicare Part D: Transition Fill Process

POLICY NUMBER: CO.MCR.257.08

I. PURPOSE STATEMENT

The purpose of this policy is to describe Prime Management LLC, (Prime), guidelines for a transition policy that is timely, accurate, and compliant with all relevant CMS regulations and guidance.

Prime Management LLC, (Prime), a subsidiary of Prime Therapeutics LLC, follows the regulations and guidelines established by the Centers for Medicare & Medicaid Services (CMS) for implementing and maintaining an appropriate medication transition process for Enrollees whose current prescribed Part D drugs are not on Prime's formulary. The purpose of providing a Transition Fill is to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated.

II. SCOPE AND APPLICABILITY

Legal entity

- | | |
|---|---|
| <input type="checkbox"/> Prime LLC | <input type="checkbox"/> Prime State Government Solutions LLC |
| <input checked="" type="checkbox"/> Prime Therapeutics Management LLC | <input type="checkbox"/> Granite Alliance Insurance Company |
| <input type="checkbox"/> Prime Therapeutics Pharmacy LLC | |

Business division

- | | |
|---|---|
| <input type="checkbox"/> Enterprise function (applies to all) | <input type="checkbox"/> Specialty & Clinical Solutions—Carve-out Rebates |
| <input type="checkbox"/> Dispensing Pharmacies | <input type="checkbox"/> Specialty & Clinical Solutions—Clinical Programs |
| <input type="checkbox"/> Medical Pharmacy | <input type="checkbox"/> State Government Solutions |
| <input checked="" type="checkbox"/> PBM Solutions | |

Line of business

- | | | |
|--|---|---|
| <input type="checkbox"/> Medicare Part B | <input type="checkbox"/> Medicare Part C (Medicare Advantage) | <input checked="" type="checkbox"/> Medicare Part D |
| <input type="checkbox"/> Medicaid | <input type="checkbox"/> Health Insurance Marketplace | <input type="checkbox"/> Commercial |

Other legal entity, product and/or function

All Medicare Part D Plans on SS&C Adjudication Platform

III. RELEVANT LAW, REGULATION AND/OR GUIDANCE

<https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf>

IV. TERMS AND DEFINITIONS

Centers for Medicare & Medicaid Services (CMS)

The Centers for Medicare & Medicaid Services (CMS) is the division of the federal Department of Health and Human Services responsible for the administration and oversight of the Medicare program and works in partnership with state governments to administer various Medicaid programs at the State level. Coverage Determination

Coverage Determination means any decision made by or on behalf of Prime regarding payment or benefits to which an Enrollee believes he or she is entitled.

Enrollee

An Enrollee means a Part D eligible individual who has elected a Part D plan offered by Prime or a Prime client.

Negative Formulary Changes

Negative Formulary Changes include (1) removal of a drug from a formulary; (2) increasing the cost-sharing status of drug on the formulary subsequent to a change in tier; (3) adding, or making more restrictive prior authorization requirements, quantity limits, or step therapy requirements; (4) imposing other restrictions on a drug that require CMS approval; and (5) the expiration of an approved exception.

Non-Formulary Drug

For purposes of this Transition Fill Policy, a Non-Formulary Part D drug means: (1) Part D drugs that are not on Prime's formulary, and (2) drugs previously approved for coverage under an exception once the exception expires.

Protected Classes

The six categories of drugs that Part D sponsors must include all or substantially all drugs in the category on their formularies: immunosuppressant (for prophylaxis of organ transplant rejection), antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes.

Transition Fill

A one-time/temporary fill for a medication for certain Enrollees who are prescribed Part D drugs that represent ongoing therapy with that drug, but that are Non-Formulary.

Transition Period

The first 90 calendar days an Enrollee is enrolled in the Medicare Part D plan. Since certain Enrollees may join a plan at any time during the year, the timeframe begins on an Enrollee's first effective date of coverage.

V. STANDARDS

1. **General Transition Requirements** - Prime provides a Transition Fill to certain Enrollees who present at a network pharmacy with a prescription for a Non-Formulary Drug.
 - A. Enrollees who may be eligible for a Transition Fill include:
 1. New Enrollees enrolled into a Prime Part D plan following the annual coordinated election period;
 2. Newly eligible Medicare beneficiaries enrolled into a Prime Part D plan;
 3. Enrollees who switch from one plan to another after the beginning of the contract year;
 4. Enrollees with an effective enrollment date of either November 1 or December 1 are provided a 90-day transition period extending across the following contract year;
 5. Current Enrollees affected by Negative Formulary Changes across contract years; and
 6. Enrollees residing in long-term care (LTC) facilities.

- B. If an Enrollee leaves a Prime plan and re-enrolls during the original 90-day Transition Period, the Transition Period begins again with the new effective date of enrollment.
- C. Transition Fills are available to Enrollees whose current drug therapy:
1. Is not on a Prime's formulary;
or
 2. Is on the formulary but subject to prior authorization (PA), step therapy (ST), or quantity limit (QL) edits based on the Prime utilization management (UM) program.
- D. Transition Fills are available to current Enrollees whose drugs will be affected by Negative Formulary Changes in the upcoming year, Prime will:
1. Provide a transition process at the start of the new contract year; or
 2. Effectuate a transition prior to the start of the new contract year.
- E. Transition Fills allow Enrollees to leave the pharmacy with their current therapy and have sufficient time to work with their medical provider to switch to a therapeutically appropriate formulary alternative or to request a Coverage Determination.
- F. Prime looks at prior drug claims for a minimum of 108 day look-back period to adequately document an Enrollee's ongoing drug therapy. If Prime is unable to distinguish between a new and an ongoing Non-Formulary prescription for a new Enrollee, Prime provides a Transition Fill to the Enrollee at the point-of-service (POS).
- G. For Protected Classes of drugs that are subject to prior authorization (PA) or step therapy (ST) on new start, if Prime provides an initial fill because it cannot determine at the POS that the Enrollee is not currently taking the Protected Class medication, Prime will not apply any PA or ST requirements after the first fill has been provided.
- H. Transition Fill processing and messaging within the adjudication platform.
1. For new Enrollees, all transition eligible fills of any Non-Formulary Drug or drug with utilization management (UM) are processed using the new member Transition Fill logic. The Prime adjudication system responds to the pharmacy with a message that this claim is a Transition Fill and provides the information to communicate to the Enrollee that the next fill will require a Coverage Determination. If a protected class drug is subject to PA or ST and Prime cannot determine at the POS whether an Enrollee is currently taking a drug (e.g., new Enrollee filling a prescription for the first time), Prime shall generally treat such Enrollee as currently taking the drug and on new starts, the adjudication system will process the claim as a continuation of therapy and no messaging to the pharmacy or transition fill letter will be generated to the Enrollee.
 2. For existing Enrollees in the first 90 days of the new plan year, if the drug is no longer formulary or has UM edits, all eligible transition fills of the drug are processed through the existing member Transition Fill logic. The Prime adjudication system responds to the pharmacy with a message that this claim is a Transition Fill and provides the information to communicate to the Enrollee that the next fill will require a Coverage Determination.

3. The pharmacy may only resolve patient safety edits at the POS. If a pharmacy needs additional assistance on a Transition Fill claim, the pharmacy is required to call the Prime Contact Center for resolution.

I. Request for Non-Formulary Exception

1. Prime has procedures for medical review of Non-Formulary drug requests, and when appropriate, a process for switching new Enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination, as described below.

2. Prime will process exception requests made by an Enrollee, his/her authorized representative, prescribing physician, or another prescriber consistent with CMS requirements outlined in "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance" (Released February 2019) sections 40.5.2 Formulary Exceptions I and 40.5.3

Supporting Statements for Exception Requests for medical review of Non-Formulary Drug requests and to determine whether to approve or deny the request, if appropriate, based on the exception criteria established for the Non-Formulary drugs.

3. Should Prime deny an exception request, the Enrollee and his/her prescriber will be sent a Notice of Denial of Medicare Prescription Drug Coverage that includes the information regarding appeal rights and description about appropriate formulary alternatives that must be satisfied for approval. Enrollee may switch to these therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

4. Upon request by Enrollee, his/her authorized representative, prescribing physician, or other prescriber, Prime will make available prior authorization or exception request forms for completion through a variety of mechanisms, including mail, fax, email, and on and on the appropriate plan web site.

2. **Transition Fill in Retail Setting** - At any time within the first 90 days of coverage, Prime provides a temporary fill of at least a month's supply (30 day) of Transition Fill to accommodate the immediate needs of the Enrollee at a retail setting.

A. Prescriptions written for a supply less than a month's supply (30 day), the written amount will be dispensed B. Prime allows an eligible Enrollee to receive multiple fills to provide for at least a month's supply (30 days) of medication.

C. If the smallest available marketed package exceeds a 30-day supply, Prime provides a Transition Fill for the smallest available package size. D. Prime may provide an extension of the Transition Period, on a case-by-case basis, to the extent that an Enrollee's exception request or appeal has not been processed by the end of the minimum Transition Period and until such time that a transition has been made (either through a switch to a formulary drug or a decision on an exception request).

3. **Transition Fill in Long Term Care Setting** - At any time within the first 90 days of coverage, Prime provides a temporary fill of at least a month's supply (31 days) of Transition Fill to accommodate the immediate needs of the Enrollee..

A. Prescriptions written for a supply less than a month's supply (31 days), the written amount will be dispensed.

B. Prime allows an eligible Enrollee to receive multiple fills to provide for at least a month's supply (31 days) of medication.

C. If the smallest available marketed package exceeds a 31-day supply, Prime provides a Transition Fill for the smallest available package size.

D. If an Enrollee in a Long-Term Care (LTC) setting is outside the 90-day Transition Period, Prime provides a 31-day emergency supply of transition eligible drugs, unless the prescription is for less than a 31-day supply, while an exception or PA is requested and processed.

E. Prime allows for early refills for Enrollees being admitted to or discharged from an LTC facility.

F. Enrollees experiencing a level of care change may access a refill upon admission or discharge to an LTC facility. Enrollees in need of a one-time Transition Fill, or who are prescribed a Non-Formulary Drug as a result of a level of care change, can be placed in transition via a National Council for Prescription Drug Plans (NCPDP) pharmacy submission clarification code (SCC) via manual override at POS or by contacting Prime Call Center for an override.

G. Prime may provide an extension of the Transition Period, on a case-by-case basis, to the extent that an Enrollee's exception request or appeal has not been processed by the end of the minimum Transition Period and until such time that a transition has been made (either through a switch to a formulary drug or a decision on an exception request).

4. Edits for Transition Fills

A. Prime automatically provides a Transition Fill of Non-Formulary Drugs, or drugs subject to ST or PA edits, in order to accommodate the immediate needs of an Enrollee during his or her Transition Period.

B. Prime provides a Transition Fill except where the following edits apply to the claim:

1. Determination of Part A or Part B vs. Part D coverage; the claims system sends a message to the pharmacy to inform the pharmacy of the reason for the edit and the additional required action on the part of the pharmacy to ensure Enrollee's transition fills for needed medications are appropriately dispensed. In the case of Part A versus D drugs, a coverage determination to confirm an Enrollee's Medicare hospice enrollment status if indicated in the CMS provided beneficiary enrollment file and confirm the use of the drug claim that is in one of the four hospice eligible categories, analgesic, anti- nausea, laxative, or anti-anxiety is required prior to payment.
2. Prevent coverage of a non-Part D drug (e.g., excluded drugs such as a drug that may be used for sexual dysfunction, or formulary drugs dispensed for an indication that is not medically accepted).
3. Promote safe utilization of a Part D drug (e.g., a maximum daily dose as recognized by FDA supported literature has been exceeded, refill too soon), subject to Prime's policy to allow multiple fills to provide for the full amount of medication allowed during a Transition Fill; Prime ensures that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling. The enrollee is allowed refills up to the days' supply allowed in the benefit.
4. Beneficiary-level opioid point-of-sale claim edits.

5. **Cost Sharing** - Prime follows the following policies for cost sharing amounts charged to Enrollees for Transition Fills:
 - A. For Low Income Subsidy (LIS) Enrollees, Prime ensures that cost-sharing for a Transition Fill does not exceed the statutory maximum co-payment amounts.
 - B. For non-LIS Enrollees, Prime charges:
 1. The same cost sharing for Non-Formulary Part D drugs provided during the Transition Period that would apply for Non-Formulary drugs approved through a formulary exception, and
 2. The same cost sharing for formulary drugs subject to UM edits provided during the transition that would apply once the UM criteria are met.
6. **Written Notification to Enrollees and Providers** - Prime sends written notice to each Enrollee and prescriber who received a Transition Fill. Notice is sent via U.S. first class mail within three (3) business days of adjudication of a Transition Fill.
 - A. The notice includes, but is not limited to, the following information:
 1. An explanation that the Transition Fill provided is temporary;
 2. Instructions for working with Prime and the Enrollee's prescriber to satisfy UM requirements or to identify appropriate therapeutic alternatives that is on the formulary;
 3. An explanation of the Enrollee's right to request a formulary exception, the timeframes for processing the exception, and the Enrollee's right to request an appeal if Prime issues an unfavorable decision; and
 4. A description of Prime's procedures for requesting a formulary exception.
 - B. Prime provides a summary of the written transition notice to the Enrollee's prescriber of record, including a description of Prime's procedures for requesting a formulary exception.
 - C. For LTC residents dispensed multiple supplies of a Part D drug in increments of 14 days-or-less, the written notice is provided within three (3) business days after adjudication of the first temporary fill. Prime ensures that reasonable efforts are made to notify prescribers of affected Enrollees who receive a transition notice.
 - D. Prime uses the CMS Model Transition Notice.
 - E. Prime ensures that PA and exception request forms are available through multiple means including mail, email, fax, phone, and on the appropriate plan web site.
7. **Notice of Transition Process** – Prime's Medicare Part D Transition Fill Process Policy is available to Enrollees on Prime Medicare Part D web site. The policy is also available in Prime, pre and post enrollment marketing materials, and upon request by an Enrollee or prescribing physician. Enrollees can also access the Prime Medicare Part D Transition Fill Process policy via a link from Medicare Prescription Drug Plan Finder to the plan's website.
8. **Pharmacy and Therapeutics Committee** - The Pharmacy and Therapeutics (P&T) Committee maintains a role in the transition process.
 - A. The P&T Committee reviews and recommends all formulary ST and PA guidelines for clinical considerations.

B. The P&T Committee reviews and recommends procedures for medical review of Non-Formulary drug requests, including the exception process and, when appropriate, a process for switching new Prime Enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

VI. RELATED ADDENDUM AND/OR SOP
N/A

Revision history			
Revision Number	Revision author(s)	Revision summary	Revision date
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3	Jill Nunnally	Annual review and rebranding	5/14/24

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Policy approval
This Policy was formally reviewed and approved by the business function as follows:
Jill Nunnally, AVP GP Pharmacy & Clinical Services, Medicare Part D 5/15/24