

Contract Number: H6750



**Pharmacy Services Department
Pharmacy Policy and Procedures
Revised 6/2022
Approved: J. MacAuley**

Policy Name: Harvard Pilgrim Health Care 2023 Pharmacy Transition Policy

Business Owner: Senior Manager, Pharmacy Operations & Programs

Reference: Regulatory, Departmental Process

Summary: This document outlines the operational processes to implement a formulary transition plan.

OBJECTIVE:

To avoid interruption in therapy, timely access to a temporary supply of medication will be provided to enrollees consistent with 42 CFR 423. 120(b)(3). Harvard Pilgrim Health Care's transition process is for enrollees whose current drug therapies may not be included in their new Part D plan's formulary. Transition will be provided for (1) new enrollees into prescription drug plans following the annual coordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one plan to another after the start of a contract year, (4) current enrollees affected by negative formulary changes across contract years and (5) enrollees residing in Long-Term Care (LTC) facilities.

DEFINITIONS:

LTC – Long-Term Care

Non-Formulary drugs to mean: 1) Part D drug that is not on a Medicare Part D plan's formulary. A non-formulary drug may include a medication that was covered under the enrollee's prior plan but is not on the Medicare Part D formulary for the plan (i.e., non-covered Part D medication). 2) Part D drugs that are on a Medicare Part D plan's formulary but require prior authorization or step therapy, or that have an approved formulary QL lower than the beneficiary's current dose, under a plan's utilization management requirements. This is because a formulary drug that is restricted via UM requirements is essentially equivalent to a non-formulary Part D drug to the extent that the associated UM requirements are not met for a specific beneficiary. However, this definition does not apply to safety QLs, which are equal to an FDA maximum dose limit, or UM intended to prevent unsafe use of a medication consistent with FDA labeling, or UM to validate the Part D eligibility of a drug. Harvard Pilgrim Health Care will apply all transition processes to brand-new prescriptions for a non-formulary drug if it cannot make the distinction between a new prescription and an ongoing prescription at the point of sale.

POLICY:

Harvard Pilgrim Health Care administers a custom, closed-design formulary, providing coverage of both Part D drugs and certain excluded drugs as a supplemental benefit.



Harvard Pilgrim Health Care's transition period is 108 days, which starts on the date of the member's effective enrollment date or following the annual coordinated election period for current enrollees affected by negative formulary changes from one contract year to the next. This transition policy extends across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and needs access to a transition supply. In the Outpatient (Retail, Mail Order, Home Infusion) setting, new enrollees and current enrollees affected by negative formulary changes are entitled to up to a 30-day supply, with multiple fills as necessary, of non-formulary Part D drugs. In the Long-Term Care (LTC) setting, these enrollees are entitled to a maximum of a 31-day supply, with multiple fills as necessary, of non-formulary Part D drugs. Current enrollees in need of an Emergency Supply in a LTC setting are entitled up to a one-time fill of up to a 31-day supply of non-formulary Part D drugs. The transition policy applies to drugs filled at pharmacies within the Harvard Pilgrim Health Care network.

PROCEDURES:

I. Transition Process

The 108-day transition period starts on the member's effective date. Current enrollees are determined to have been negatively impacted by a formulary change from one contract year to the next if the transition claim is for a drug that the enrollee filled within the previous 180 days. During a member's transition period, at the point of sale, system edits that effect prior authorization, step-therapy or quantity or dosage limitations are automatically overridden by a point of service transition edit established with OptumRx. Transition eligible members will be allowed fills for drugs that are non-formulary or subject to utilization management (prior authorization, step therapy, or quantity limits).

OptumRx will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at the point-of-sale.

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, Harvard Pilgrim Health Care will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.

In the retail setting, the transition policy provides for a one-time temporary fill of a least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case multiple fills will be provided up to a total of a month's supply of medication) anytime during the first 108 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.



In the long-term care setting: (1) the transition policy provides for a one-time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should be dispensed incrementally as applicable under 42 CFR 423.154 and with multiple fills provided if needed during the first 108 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested and (3) for enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.

II. Transition Extension

Harvard Pilgrim Health Care will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that the enrollee's exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).

III. Implementation Statement

• Claims Adjudication System

OptumRx has systems capabilities that allow them to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee 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.

• Pharmacy Notification at Point-of-Sale

OptumRx provides a free text message in the pharmacy response identifying a fill as a transition fill and other information related to authorization processing as needed. The pharmacy is also provided NCPDP-approved message codes in the pharmacy response. NCPDP reject codes only relative to transition are delivered to the pharmacy and are dependent on pharmacy's software to apply the appropriate message. When a transition supply claim is paid through the system, pharmacies are notified via an electronic message informing them that fill was part of a transition supply. If the claim encounters a valid transitional reject, a message is returned to the pharmacy to indicate the reason for the rejection.

• Edits During Transition

The only utilization management edits that apply during transition at the point-of-sale are: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits are resolved at point-



of-sale.

Refills are allowed 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.

As outlined in 42 CFR 423.153(b), Point-of-Sale (POS) PA edits are in place 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 whose medical use or class is excluded from coverage or otherwise restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) drugs as an example). Early refill edits continue to be applied during transition, with the exception of transition fills due to level of care changes.

- **Pharmacy Overrides at Point-of-Sale**

During the member's transition period, all edits (with the exception of those outlined above) associated with non-formulary drugs are automatically overridden at the point-of-sale. Pharmacies can also contact OptumRx's Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. The Help Desk can also accommodate overrides at point-of-sale for emergency fills for members with level of care changes.

IV. Cost-Sharing for Transition Supplies

For non-LIS enrollees, transition supplies for non-formulary Part D drugs process with a cost share that is consistent with the tier on which drugs approved as formulary exceptions process [in accordance with 42 CFR §423.578(b)]. For drugs that are on formulary but are subject to utilization management, transition supplies process at the cost-share associated with the tier on which the drug is covered on the formulary. This is the same cost-share that would apply if the utilization criteria are met. For low-income subsidy (LIS) eligible enrollees, the temporary supply of drugs provided under the transition process will never exceed the statutory maximum co-payment amounts.

V. Written Notifications

Written notice, consistent with CMS transition requirements, is sent to both members and their prescribers.

Member transition notifications are generated by OptumRx. Harvard Pilgrim Health Care uses the CMS model Transition Letter, which includes (1) an explanation of the temporary nature of the transition supply an enrollee has received; (2) instructions for working with the plan sponsor and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary; (3) an explanation of the enrollee's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. OptumRx generates and sends the transition letter within three business days of adjudication of a temporary transition fill. Members receive one letter for each applicable drug filled within the transition period. Letters are not sent to members who received a transition fill for a protected class drug that is either non-



formulary or is subject to PA or step therapy requirements as subsequent fills will continue to be authorized throughout the benefit year.

For long-term care residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less, consistent with the requirements under 42 CFR 423.154(a)(1)(i), the written notice is provided within 3 business days after adjudication of the first temporary fill.

Reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice. OptumRx generates and mails prescribers a copy of the member transition notification.

This transition policy is available to enrollees via a link from Medicare Prescription Drug Plan Finder to the Harvard Pilgrim Health Care website and is also included in pre- and post-enrollment marketing materials as directed by CMS. This policy is also submitted to CMS as required.

VI. Pharmacy & Therapeutics (P&T) Committee Role

Harvard Pilgrim Health Care P&T Committee reviews and recommends all Harvard Pilgrim Health Care formulary step therapy and prior authorization guidelines for clinical considerations. The P&T Committee, in accordance with Chapter 6 of the Medicare Prescription Drug Benefit Manual, also reviews and recommends procedures for medical review of non-formulary drug requests.

VII. Exception Requests

Harvard Pilgrim Health Care has procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination, as described below.

Harvard Pilgrim Health Care , reviews exception requests consistent with CMS requirements outlined in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance. Harvard Pilgrim Health Care reviewers utilize exception criteria established for non-formulary Part D drugs. When evaluating an exception request for transitioning members, the medical review procedures consider the clinical aspects of the drug, including any risks involved in switching to a therapeutically appropriate formulary alternative. Should a request be denied, the member and prescriber will be sent written notification of the denial, including any specific criteria or therapeutically appropriate formulary alternatives that must be satisfied for approval. A member may switch to a therapeutically appropriate formulary alternative failing an affirmative medical necessity determination.

Prior authorization forms or exception request forms are made available upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on the Harvard Pilgrim Health Care website.

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Related Documents:

- Transition Notification Letter
- File Pickup User Guide
- Sample Optum report.txt

Staff Impacted:

- Pharmacy Operations Department
- Pharmacy Utilization Management Department
- Harvard Pilgrim Health Care Customer Service Department
- Harvard Pilgrim Health Care Learning and Development (L & D) Department