



PURPOSE OF THE POLICY

The purpose of this policy is to describe Health Alliance's process for transitions and ensure that continued drug coverage is provided to new and current Part D members. The transition process allows for a temporary supply of drugs and sufficient time for members to work with their health care providers to select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity. Transition processes will be administered by OptumRx in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per [42 CFR §423.120\(b\)\(3\)](#).

STATEMENT OF THE POLICY

Health Alliance will follow this policy for members joining the Medicare Advantage Part D Benefit and Part D Pharmacy Benefit who are currently on medications which may not be coded on the Medicare D Formulary or have restrictions. This transition process will allow members to continue their current maintenance medication therapy without interruption.

PROCEDURES

1. Overview

- 1.1 The PBM, OptumRx, supports Health Alliance in administering a transition process that is in compliance with the established CMS transition requirements.
- 1.2 Health Alliance will ensure that its transition policy will apply to non-formulary drugs, meaning both
 - Part D drugs that are not on the plan's formulary; and
 - Part D Drugs that are on the plan's formulary but require prior authorization or step therapy under the plan's utilization management rules.
- 1.3 Health Alliance will ensure that its policy addresses 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.
- 1.4 Also in accordance with CMS requirements, Health Alliance ensures that drugs excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process. However, to the extent that the Plan covers certain Part D excluded drugs under an Enhanced benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

2. Transition Population

- 2.1 Health Alliance will maintain an appropriate transition process consistent with [42 CFR §423.120\(b\)\(3\)](#) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for:
 - new enrollees into prescription drug plans at the beginning of a contract year;
 - the transition of newly eligible Medicare beneficiaries from other coverage at the beginning of a contract year;
 - the transition of individuals who switch from one plan to another after the beginning of a contract year;

- enrollees residing in long-term care (LTC) facilities; and
- in some cases, current enrollees affected by formulary changes from one year to the next

3. Transition Period

- 3.1 CMS requires a minimum of 90 days from the start of coverage under a new plan. The 90 days are calculated from the member's Part D plan start date. Health Alliance will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. This 90 day timeframe applies to retail, home infusion, LTC and mail-order pharmacies.
- 3.2 Through OptumRx, Health Alliance 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.

4. Implementation Statement

- 4.1 Claims Adjudication System: OptumRx has systems capabilities that allow OptumRx 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.
- 4.2 Pharmacy Notification at Point-Of-Sale: Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, OptumRx will promptly implement either:
 - appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim, or
 - alternative approaches that achieve the goals intended in the messaging guidance.
- 4.3 Edits During Transition: During an enrollee's transition period, the only edits that are enforced by OptumRx's claims adjudication system are:
 - edits to help determine Part B vs. Part D coverage,
 - edits to help prevent coverage of non-Part D drugs (i.e., excluded drugs); and
 - edits to help promote safe utilization of a Part D drug (i.e., quantity limits based on FDA maximum recommended daily dose, early refill edits).
- 4.4 OptumRx will ensure that the transition policy provides 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.
- 4.5 Pharmacy Overrides at Point-Of-Sale: During the member's transition period, all edits (with the exception of those outlined in Section 4.3) associated with non-formulary drugs are automatically overridden by OptumRx's claims adjudication system at the point-of-sale.
- 4.6 OptumRx will ensure that pharmacies can override step therapy and prior authorization edits - other than those that are in place to determine Part B versus Part D coverage, prevent coverage of non-Part D drugs, and promote safe utilization of a Part D drug (e.g., quantity limits based on FDA maximum recommended dose, early refill edits) - during transition at point-of-sale.
- 4.7 Pharmacies can also contact OptumRx's Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. OptumRx can also accommodate overrides at point-of-sale for emergency fills as described in Section 6.

- 4.8 Non-Part D Transitions: All prior approval for drugs, therapies, or other services existing in Medicare or Medicaid at the time of enrollment will be honored for 180 days after enrollment and will not be terminated at the end of 180 days without advanced notice to the enrollee and transition to other services, if needed.

5. Transition Fills for new Members in the Outpatient (Retail) Setting

- 5.1 OptumRx will ensure that in the retail setting, the transition policy provides for at least a one-time, temporary 30-day fill (unless the enrollee presents with a prescription written for less than 30 days in which case the Part D sponsor must allow multiple fills to provide up to a total of 30 days of medication) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.

6. Transition Fills for New Members in the LTC Setting

- 6.1 OptumRx will ensure that in the long-term care setting:
- the transition policy provides for a 31-day fill (unless the enrollee presents with a prescription written for less than 31 days), with multiple refills as necessary, up to a 93 days' supply during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage;
 - in the long-term care setting, after the 90 day 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
 - 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.

7. Emergency Supplies and Level of Care Changes for Current Members

- 7.1 An Emergency Supply is defined by CMS as a one-time fill of a non-formulary drug that is necessary with respect to current members in the LTC setting. Current members that are in need of a one-time Emergency Fill or that are prescribed a non-formulary drug as a result of a level of care change can be placed in transition via Segment Code 5 of the Type 24 File. Health Alliance has authorized OptumRx to also accommodate a one-time fill in these scenarios via a manual override at point-of-sale.

8. Optional Medicare Part D LTC Notification Report

- 8.1 The OptumRx Medicare Part D LTC Notification Report is designed to assist Health Alliance by providing notification when a member who is not Low Income Cost-Sharing (LICS) Level 3 has a prescription filled while in a Nursing Home, LTC Facility or a Rest Home. The Plan uses this report to identify members that may be in need of a one-time emergency fill or that qualify for transition due to a level of care change.

9. Transition Across Contract Years

- 9.1 For current enrollees whose drugs are no longer on the formulary, Health Alliance will effectuate a meaningful transition by either:
- providing a transition process consistent with the transition process required for new enrollees beginning in the new contract year; or
 - effectuating a transition prior to the beginning of the new contract year.

- 9.2 OptumRx POS logic is able to accommodate Section 9.1, bullet 1 by allowing current members to access transition supplies at the point-of-sale when their claims history from the previous calendar year contains an approved claim for the same drug that the member is attempting to fill through transition. This process only applies to current members that are not otherwise placed in transition by the Plan via Segment Code 5 of the Type 24 File. To accomplish this, POS looks for Part D claims in the member's claim history that were approved prior to January 1 of the new plan year and that have the same HICL, Dosage Form, Product flag and Indicator flag values as the transition claim.

10. Transition Extension

- 10.1 Sponsor 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 their 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).

11. Cost-sharing for Transition Supplies

- 11.1 OptumRx will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS eligible enrollees, OptumRx will ensure that cost-sharing for a temporary supply of drugs provided under its transition process is based on one of the sponsor's approved cost-sharing tiers (if the sponsor has a tiered benefit design) and is consistent with cost-sharing the sponsor would charge for non-formulary drugs approved under a coverage exception.

12. Six Classes of Clinical Concern

- 12.1 Per CMS guidance, members transitioning to a Plan while taking a drug within the six classes of clinical concern must be granted continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in the Plan. Utilization management restrictions and/or non-formulary status, which may apply to new members naïve to therapy, are not applied to those members transitioning to the Medicare Part D plan on agents within these key categories. The six classes include:
- Antidepressant;
 - Antipsychotic;
 - Anticonvulsant;
 - Antineoplastic;
 - Antiretroviral; and
 - Immunosuppressant (for prophylaxis of organ transplant rejection).

13. Member Notification

- 13.1 OptumRx provides the Plan (via FTP) with a daily file called the Transition Notification File. The Transition Notification File, which contains claims data and other member information, provides the Plan with all of the information needed to contact members and providers regarding transition fills. Sponsor will send written notice via U.S. first class mail to enrollee within three business days of adjudication of a temporary fill.
- 13.2 The notice must include
- an explanation of the temporary nature of the transition supply an enrollee has received;

- instructions for working with the plan sponsor and the enrollee's prescriber to identify appropriate therapeutic alternatives that are on the plan's formulary;
 - an explanation of the enrollee's right to request a formulary exception; and
 - a description of the procedures for requesting a formulary exception
- 13.3 Sponsor will 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 45-day review.

14. Prescriber Notification

- 14.1 As provided in [42 CFR section 423.120\(b\)\(3\)\(v\)](#), CMS mandated that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice under paragraph (b)(3)(iv). To support the plan with this requirement, OptumRx developed a Prescriber Transition Notification template and a File Specification document for plans to utilize. All of the member, prescriber and claim details required to populate the Prescriber Transition Notification template are included in the Transition Notification Files that are sent to the plan daily, as described in section 13.1 above.
- 14.2 Prescriber Transition Notifications are mailed to the prescriber at the same time the transition notice is mailed to the member.

15. PDE Reporting

- 15.1 Since this is a CMS required process, any drugs dispensed that qualify under the transition period are reported as covered Part D drugs with appropriate Plan and member cost sharing amounts on the Prescription Drug Event (PDE).

16. CMS Submission

- 16.1 Health Alliance will submit a copy of its transition process policy to CMS annually.

17. Pharmacy and Therapeutics Committee

- 17.1 The Health Alliance Pharmacy and Therapeutics Committee (P&T) maintains a role in the transition process in the following areas:
- The P&T committee reviews and recommends all formulary step therapy and prior authorization guidelines for clinical considerations; and
 - The P&T committee reviews and recommends procedures for medical review of non-formulary drug requests, including the exception process.

18. Exception Process

- 18.1 Health Alliance follows an overall transition plan for Medicare Part D members; a component of which includes the exception process. Health Alliance's exception process integrates with the overall transition plan for these members in the following areas:
- Health Alliance's exception process complements other processes and strategies to support the overall transition plan. The exception process follows the guidelines set forth by the transition plan when applicable.
 - When evaluating an exception request for transitioning members, the Plan's exception evaluation process considers the clinical aspects of the drug, including any risks involved in switching, when evaluating an exception request for transitioning members.
 - The **Medicare D Medical Exception / Tier Exception / Coverage Determination** policy includes a process for switching new Medicare Part D plan members to

therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

- 18.2 Health Alliance will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan web sites.

19. Health Alliance Medical Plans Pharmacy Policy [Web address](#)

APPENDIX

- *Glossary*
- *POS Transition Flow Diagram*
- *Health Alliance Prior Authorization Form*