PrimeTime Health Plan's Medicare Part D 2023 Transition Supply Policy

Regulation/Requirement:	42 CFR §423.120(b)(3) 42 CFR § 423.154(a)(1)(i); 42 CFR § 423.578(b); Prescription Drug Manual, Chapter 6, Section 30.4; Part D Transition Letter
Purpose:	This document defines PrimeTime Health Plan's prescription drug transition policy which ensures compliance with Medicare Part D transition supply requirements.
Scope:	This Policy is applicable to the PrimeTime Health Plan's Prescription Drug Plan and its enrollees covered under CMS Contract(s) H3664.
Policy:	Where applicable and as required by CMS, PrimeTime Health Plan provides transition-eligible Medicare enrollees a temporary supply for eligible medications when the medication meets one or more of the following conditions: Not included on the Plan's formulary; or On the Plan's formulary, but are subject to utilization management rules including: Prior Authorization Required, Step Therapy or Plan-imposed Quantity Limits. The process is intended to afford enrollees and their care team sufficient time to work with their health care providers to switch to a therapeutically appropriate formulary alternative or to request an exception on the grounds of medical necessity.

IMPLEMENTATION STATEMENT
An Implementation Statement is contained within PrimeTime Health Plan's transition policy that provides a detailed explanation of how PrimeTime Health Plan/OptumRx processes transition requests within their adjudication system; how the pharmacy is notified when transition medication is processed at the point of sale; description of edits and explanation of the process pharmacies follow to resolve transition medication edits at the point of sale.

Procedure:	
Task 1:	**Transition Requirements – CMS Attestation #1**
	PrimeTime Health Plan offers this transition policy as a written description of the appropriate transition processes consistent with 42 CFR §423.120(b)(3) for our enrollees whose current drug therapies may not be included in their new Plan formulary. The Plan will maintain this policy and effectuate a meaningful transition for: 1. New enrollees into its 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; 5. Enrollees residing in long-term care (LTC) facilities; 6. In some cases, enrollees who change treatment settings due to a change in level of care. Enrollees who are undergoing a change in care are eligible for a temporary fill to ensure the continuity of needed medications across care settings. The level-of-care change automated programming identifies whether or not the member has a change in patient residence code based on most recent claim. If a level-of-care change is identified, the system can be configured to automatically override the following edits on Part D-covered drugs at the plan's discretion to allow the claim to pay: A. Refill-too-Soon B. Duplicate prescription C. Duplicate therapy D. Non-formulary E. Prior authorization (excluding Part B vs. Part D or Part D vs. Part D-excluded drugs) F. Step therapy G. Quantity limits If the member did not have a change identified by a change in patient residence code, in order to ensure that the enrollee does not have a gap in therapy, the pharmacist should call the plan's call center to notify them of the level-of-care change in order to have an authorization placed in the system allowing the claim to pay. This authorization is to address the above edits, resulting in a paid claim as determined by the plan. These authorizations are to be entered as one-time authorizations; however, if the member has subsequent level-of-care changes, additional one-time authorizations are to be entered to ensure there are no gaps in therapy.

Task 2:	**Transition Policy Submission CMS Attestation #2**
	The Plan will submit a copy of its transition policy to CMS and ensure all submissions are per CMS guidelines and that the policy conforms to the requirements of the Prescription Drug Manual, Chapter 6, Section 30.4.
Task 3:	**Transition Scope CMS Attestation #3**
	The transition process is applicable to non-formulary drugs, meaning: 1. Part D Drugs that are not on a plan's formulary; 2. Part D Drugs that are on a plan's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose under a plan's utilization management rules. The Plan 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. The Plan's coverage review and care coordination process addresses this requirement.
Task 4:	**System Capabilities - CMS Attestation #4**
	The Plan has systems capabilities that allow the plan 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.
Task 5:	**Transition Timeframes and Temporary Fills – CMS Attestation #5**
	The plan ensures that, in the retail setting, the transition policy provides for a one-time, temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply of medication, in which case the plan will allow multiple fills to provide up to a total of one month's supply 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. In some instances, greater than a month's supply will be dispensed to allow appropriate transition fills for drugs manufactured in "unbreakable packages".

Task 6:	**Cost-Sharing Considerations CMS Attestation #6**
	The Plan 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 enrollees, the plan will charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with 42 CFR § 423.578 (b) and 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.
Task 7:	**LTC Day Supply CMS Attestation #7**
	The plan will ensure that in the LTC setting: 1. The transition policy provides for a one month temporary fill of at least a month's supply of medication (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 90 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. LTC enrollees are identified based on the patient residence code submitted on claim(s). This indicator permits a refill of a month's supply of transition medication.
Task 8:	**Edits for Transition fills CMS Attestation #8**
	The plan only applies the following utilization management edits to claims at the point of sale during transition: 1. Edits to determine Part A or B versus Part D coverage; 2. Edits to prevent coverage of non-Part D drugs; 3. Edits to promote safe utilization of a Part D drug. Step Therapy and Prior Authorization edits will be resolved at Point of Sale (POS) through system logic.

Task 9:	**Quantity Limits CMS Attestation #9**
	The plan will ensure 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.
Task 10:	**New Prescriptions Versus Ongoing Drug Therapy CMS Attestation #10**
	The plan applies 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 point of sale. The system will allow for refills of a transition eligible drug at the point of sale to ensure enrollees receive at least a one-month supply of a transition eligible drug. In some cases, more than a one-month supply will be extended when the drug is prepackaged and cannot be dispensed at a lower day supply.
Task 11:	**Transition Notices CMS Attestation #11**
	The plan will send written notice consistent with CMS transition requirements. A written CMS approved notice is sent via U.S. First Class Mail to the enrollee and the prescriber within three (3) business days of adjudication of a temporary transition fill. The notice includes: 1. An explanation of the temporary nature of the transition supply that the enrollee has received; 2. Instructions for working with the plan 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; 4. A description of the procedures for requesting a formulary exception, which includes expected timeframes to decision the request, and information on the right to appeal. 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 must be provided within three business days after adjudication of the first temporary fill.
Task 12:	**Exception Request Forms CMS Attestation #12**
	Enrollees and prescribers may call Customer Service lines and request prior authorization or exception request forms via a variety of mechanisms including mail, fax, or email. They may also download the forms from PrimeTime Health Plan's website.

Task 13:	**Transition Across Contract Years CMS Attestation #13**
	The plan will extend its transition policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of November 1 or December 1 and need access to a transition supply.
Task 14:	**Public Notice of Transition Process CMS Attestation #14**
	The plan will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to the plan's web site and include in pre-and post-enrollment marketing materials as directed by CMS.
Task 15:	**Transition Extension CMS Attestation #15**
	The Plan will 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.) Extensions need to be initiated by the beneficiary, beneficiary's authorized representative, or prescriber. Requests may be made in writing, telephonically, or by email or fax.
Task 16:	**Current Enrollees CMS Attestation #16**
	For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the plan 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. Systems ensure a current enrollee is provided with a 90 day cross-plan year transition window at the beginning of each contract year. During this time, a current enrollee will be provided with a transition supply of an eligible drug unless the drug was previously filled as a transition supply. The system queries current enrollee's previous utilization through a look-back window that begins on the last day of the previous plan year and extends back 120 days. If the enrollee had previous utilization, they are eligible for a transition fill if the medication's coverage status changed across the plan year. If the enrollee is lacking utilization within the look-back window, this will preclude a transition supply from being extended to a current enrollee during their cross-plan year window, as that enrollee is not transition eligible.

Attachment A

Transition Supply – Plan Implementation Statement
PrimeTime Health Plan with OptumRx

During the transition period, OptumRx's claims system allows a transitional fill for all products identified as transition-eligible. The coding and claims processing system allows temporary supplies of non- formulary Part D drugs (including Part D drugs that are on the formulary but require PA, ST, QL-type PA under UM rules). The claims processing system has an automated configuration that determines whether or not the criteria for a transition supply is met. Claims are processed at POS and do not require additional action from the pharmacist, unless an allowable edit is in place. This accommodates the immediate needs of an enrollee, as well as allowing the plan and/or enrollee sufficient time to work with 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.

MESSAGING:

1. If a transition fill is effectuated, the dispensing pharmacy receives:
    a. A free text message in the pharmacy response identifying this as a transition fill and other information related to authorization processing as needed.
    b. NCPDP-approved message codes in the pharmacy response. The pharmacy only receives NCPDP reject codes relative to transition and is dependent on pharmacy's software to apply appropriate message.
    c. 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 reason for rejection.
    d. If the claim is submitted for greater than the transition supply allowed or the transition day supply remaining for that member/drug combination, the claim will reject and a message is returned on the claim that defines the number of days remaining in their transition supply. This allows the pharmacy to reduce the days' supply to receive a paid transition claim.
2. Once the transition period has ended, the system rejects those claims for which products are non-formulary, need PA, or exceed plan limitations.

TRANSITION NOTIFICATION

1. Transition supplies are identified by the adjudication system based on specific indicators on the claim.
2. For "Formulary Change across Contract Year" and "Level-of-Care Emergency Fill" transition claims, each claim is stamped with a transition claim indicator.
3. These indicators are used to define the type of transition and the reason for the transition, as defined in the CMS transition letter template (i.e., non-formulary, PA, ST, etc.).

4. If a temporary fill is provided for a Part D drug under the applicable transition process, an appropriate written notice regarding the transition process is mailed within three (3) business days of the temporary fill submitted by provider.
5. OptumRx sends written notice to both the enrollee and the prescriber via U.S. first-class mail within three (3) business days of adjudication of a temporary fill. The notice must include:
    a. Explanation of temporary nature of transition supply an enrollee has received
    b. Instructions for working with plan sponsor and enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary
    c. Explanation of enrollee's right to request a formulary exception
    d. Description of procedures for requesting a formulary exception
6. For LTC residents dispensed multiple supplies of a Part D drug in increments of 14 days or less, consistent with the requirements of 42 CFR $423.154(a)(1)(i), written notice is to be provided within three (3) business days after adjudication of first temporary fill.

QUANTITY LIMITS, REFILL-TOO-SOON, AND SAFETY EDITS

OptumRx's transition process policy provides for refills of transition prescriptions dispensed for less than the written amount due to QLs for safety purposes or drug utilization edits that are based on approved product labeling.

1. Only certain drug UM edits are applied during a beneficiary's transition period at POS.
2. Drug utilization management edits that are appropriate during this transition period include: edits to help determine Part A or B vs. Part D coverage; edits to prevent coverage of non-Part D drugs (i.e., excluded drugs); or edits to promote safe utilization of Part D drugs (i.e., Maximum Allowable Daily Dose (MADD) edits based on FDA maximum recommended doses, early refill edits); or edits to maximize appropriate dose.
3. OptumRx/PrimeTime Health Plan applies edits to certain non-six clinical class drugs, MADD edits, B vs. D administrative PA edits, and early refill edits during transition. Resolution of edits is made by the dispensing pharmacist at POS by either: (1) resubmitting claim with revised/corrected information, or (2) calling the Member Services Department/Pharmacy Help Desk. Edits that are placed on the formulary vary by formulary (CMS-approved) and benefit design.
4. Edits applied during transition are managed and resolved through POS and review activity.
5. If any non-formulary, PA, ST, or QL edit is overridden at POS for transition purposes only, but not permanently, the beneficiary is notified so that they can begin the exception process, if necessary. Notification occurs via U.S. first-class mail to the enrollee within three (3) business days of adjudication of a temporary fill. Notification specifics are outlined under "Transition Notification" section.
6. Additional ST-type PA or PA edits are implemented during transition if such edits can be resolved at POS.
7. All non-formulary, PA, and ST edits are subject to exception request and appeal. Beneficiaries are made aware of any edits that result in a prescription being filled differently than originally written, as well as their right to request an exception.

8. PrimeTime Health Plan expeditiously processes such exception requests so that beneficiaries do not experience unintended interruptions in medically necessary Part D drug therapies and/or inappropriately pay additional cost sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.
    a. All non-formulary, PA, ST, or QL edits (not including Part B vs. Part D or Part D vs. Part D-excluded prior authorizations, edits to reject non-part D drugs, QLs for safety reasons, and early refill edits) are overridden during the transition period to allow multiple fills up to the overall transition days' supply limit. Multiple refills of a transition supply may therefore be obtained up to the maximum allowable days' supply of a transition supply.
    b. Enrollees must be allowed to refill a transition supply of a non-formulary Part D drug if the prescription is dispensed for less than the written amount due to QLs for safety purposes or drug utilization edits that are based on approved product labeling.
    c. All non-formulary, PA, ST, or QL edits are to be resolved at point-of-service adjudication. No "hard edits" are utilized in order to manage transition supplies. Since UM edits (except Part B vs. Part D or Part D vs. Part D-excluded prior authorizations, edits to reject non-part D drugs, QLs for safety reasons, and early refill edits)) are overridden to allow a transition fill during the first 90 days of enrollment, there is no need for retail, home infusion, safety-net, or ITU pharmacists to enter an override. These claims pay without any additional input from the submitting pharmacist, and the enrollee, therefore, never leaves the pharmacy without a transition supply.

PROTECTED CLASS DRUGS

1. Enrollees who receive a transition supply of a PA or ST (formulary) drug in the "Six Classes of Clinical Concern" are automatically grandfathered to continue taking that medication throughout the benefit year.
2. They are not to be considered "new starts" and do not need to go through coverage determination and exception process in order to continue on medication.
3. These members are not to be sent a transition letter since they will continue on their therapy without interruption.

TRANSITION REPORTING AND DOCUMENTATION

1. OptumRx's manager of Medicare communication or their designee provides relevant client advisor personnel the following reports and information quarterly, or more frequently, as required by the client:
    a. Transition fulfillment report outlining transitions granted and notices sent
    b. Compliance reporting for information regarding timeliness of fills and transition notice fulfillment
2. OptumRx also provides the Part D sponsor with data including support of the Transition Monitoring Program Analysis activity.