

Policy Title:	Pharmacy Benefits Transition Process	Number & Version:	RX03 V.10
Functional Unit:	Pharmacy	Effective Date:	01/01/2021
Policy Owner (Title):	Clinical Pharmacist	Page Number:	1 of 8

I. POLICY STATEMENT and PURPOSE

It is the policy of the Company, acting on behalf of client organizations, to contract with an external Pharmacy Benefits Manager (PBM) to administer the Pharmacy Benefits Transition Process on the Company’s behalf. The PBM will maintain an appropriate transition process, consistent with 42 CFR §423.120(b)(3), for enrollees whose current drug therapies may not be included in their new Part D plan’s formulary, to effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual coordinated election period, (2) newly eligible Medicare beneficiaries transitioning 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.

This transition policy and process is applicable to non-formulary drugs, meaning both (1) Part D Drugs that are not on the Plan’s formulary and (2) Part D drugs that are on the Plan’s formulary but require prior authorization or step therapy, or that have an approved quantity limit (QL) lower than the beneficiary’s current dose, under a Plan’s utilization management rules. Drugs excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process.

II. OWNERSHIP & TRAINING

The Pharmacy Department is responsible for administration of this Policy and will train staff who have responsibilities under this Policy annually and on an “as needed” basis relative to any revisions that result in a procedural change.

III. PROTOCOLS

The Company’s contracted PBM will adhere to the following Transition Process:

Procedure (Implementation Statement):

a. New Prescriptions Presented During Transition Period

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

- i. Transition window: Enrollees will be eligible to receive at least a one-time temporary fill of a non-formulary Part D drug any time during the first 90 days of their enrollment, beginning on the enrollee’s effective date of coverage for

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the Centers for Medicare & Medicaid Services (CMS) contract year. This 90-day time period applies to retail, home infusion, long-term care (LTC), and mail-order pharmacies.

- ii. Claims adjudication system: The PBM 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. Refer to the Attachment ‘PBM POS Transition Flow Diagram’ for detail.
- iii. Pharmacy notification at point-of-sale: The PBM utilizes the current NCPDP Telecommunication Standard to provide POS messaging. The PBM reviews NCPDP reject and approval codes developed during the External Codes List (ECL) process. Pharmacy messages are modified based on industry standards.
- iv. Edits during transition: The PBM will apply only the following utilization management edits during transition at point-of-sale: 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 must be resolved at point-of-sale. The PBM has implemented point-of-sale edits to determine whether a drug is being used for a Part D medically accepted indication, or whether it is a drug or drug class that is excluded from coverage or otherwise restricted under Part D (for example, Cialis and transmucosal immediate release fentanyl). Pharmacies can also contact the PBM’s Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. The PBM can also accommodate overrides at point-of-sale for emergency fills.
- v. Utilization management edits, such as quantity limit edits for safety purposes or drug utilization edits based on approved product labeling (such as maximum FDA-recommended dose) may result in less than the prescribed amount being dispensed. In this case, refills will be made during the transition period to provide for at least a 30-day supply in a retail setting, and at least a one-month supply dispensed with multiple refills as necessary based on the dispensing increment in an LTC setting.
- vi. Transition fills for new members in the Retail setting: The PBM will ensure that, in the retail setting, plan enrollees are eligible for a one time temporary fill of at least a month’s supply of medication (unless the enrollee presents with a

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prescription written for less than a month’s supply, in which case the Part D sponsor must allow multiple fills to provide up to a total of a 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.

vii. Transition fills for new members in the long-term care (LTC) setting:

1. In the LTC setting, plan enrollees are eligible 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 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, LTC residents are eligible 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.
3. For enrollees being admitted to or discharged from an 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.
4. 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. Upon receiving an LTC claim transaction where the pharmacy submitted a Submission Clarification Code (SCC) value of “18,” which indicates that the claim transaction is for a new dispensing of medication due to the patient’s admission or readmission into a LTC facility, the PBM’s system will recognize the current member as being eligible to receive transition supplies and will only apply the point-of-sale edits described in section III(a)iv of this policy. In this instance, the Plan does not need to enter a point-of-sale override.

b. Transition Extension

- i. The PBM 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 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

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decision on an exception request). On a case-by-case basis, point-of-sale overrides can also be entered by the Plan or PBM (if authorized by the Plan to do so) in order to provide continued coverage of the transition drug(s).

c. Six Classes of Clinical Concern

- i. Per CMS guidance, members transitioning to the Plan while taking a drug within the six classes of clinical concern (as defined by CMS) 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 (Prior Authorization and/or Step Therapy), which may apply to new members who are naïve to therapy, are not applied to those members transitioning to the Medicare Part D plan on agents within these key categories. For new members, protected class drug logic will always override transition logic to process the claim. Additionally, for new members, a 120-day transition period from their member effective date with the Plan is provided.

d. Transition Notices

- i. The PBM will send written notice via U.S. First Class mail to the enrollee within three (3) business days of adjudication of a temporary transition fill. If the enrollee completes his or her transition supply in several fills, the Plan is required to send notice with the first transition fill only. 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 (3) business days after adjudication of the first temporary fill.
- ii. The Company 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. The Company will provide the PBM with a copy of the CMS-approved transition notice to use for member written notice.
- iii. The notice will include, at a minimum:
 - 1. An explanation of the temporary nature of the transition supply an 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;

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- 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.
- iv. The PBM will ensure that reasonable efforts are made to send written notice to prescribers to notify prescribers of affected enrollees who receive a transition notice. The notice provides prescribers with formulary alternatives.

e. Cost-Sharing Considerations

- i. Cost-sharing for a temporary supply of drugs provided under the 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.

f. Transition Across Contract Years

- i. For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the PBM 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. The PBM’s point-of-sale system is able to allow option 1 by allowing current members to access transition supplies at the point-of-sale when their claims history from the previous contract year contains an approved claim for the same drug the member is attempting to fill through transition and the drug had a negative formulary change from one plan year to the next. To accomplish this, the system 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 value as the transition claim. Additionally, if a brand medication is being filled under transition, the previous claim must also be brand (based on NSDE marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).
- ii. Negative changes are changes to a formulary that result in a potential reduction in benefit to members. These changes can be associated with removing the

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covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management.

- iii. The PBM will extend the transition policy across contract years should a beneficiary enroll into a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.

g. Public Notice of Transition Process

- i. The Company will make this transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to the Company’s website and include it in pre- and post-enrollment marketing materials, as directed by CMS.

h. Prior Authorization Forms

- i. The Company makes prior authorization or exceptions request forms available upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and plan web sites. The Company posts printable and secure online versions of the prior authorization or exceptions forms on its member website and provider portal.

i. Prior Authorization and Exception Process

- i. The PBM will review coverage determination requests (including prior authorization and exception requests) for medical necessity. Prior authorization and exception requests for non-formulary medications are determined in accordance with the PBM’s policy for Medicare Part D Coverage Determinations. When evaluating an exception request for transitioning members, the PBM’s evaluation process considers the clinical aspects of the drug, including any risks involved in switching. The exception policy includes a process for switching new Medicare Part D plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. Enrollees can also use the appeals process to request coverage after an adverse determination.

IV. REGULATORY REFERENCES / CITATIONS

42 CFR §§423.120, 423.154, 423.578 Medicare Prescription Drug Benefit Final Rule
 Medicare Prescription Drug Benefit Manual, Chapter 5 – Benefits and Beneficiary Protections
 Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements

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Medicare Prescription Drug Benefit Manual – Parts C & D Enrollees Grievances, Coverage Determinations, and Appeals Guidance

V. RELATED POLICIES / PROCEDURES

None

VI. ATTACHMENTS

Attachment 1 – PBM POS Transition Flow Diagram

APPROVALS:

	Printed Name	Signature
Functional Unit Executive:	<u>Catherine Linsin</u>	_____
Chief Compliance Officer:	<u>Erin Venable</u>	_____
Chief Legal Officer:	<u>Gail Halterman</u>	_____

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	April 2011	Sandy Burgess, PharmD	Original Issue
02	April 2012	Sandy Burgess, PharmD	Update per CMS specifications for CY2013 Transition Process
03	May 2013	Sandy Burgess, PharmD /Melita Pasagic, PharmD	Update per CMS specifications for CY2014 Transition Process
04	May 2014	Sandy Burgess, PharmD	Update per CMS specifications for CY2015 Transition Process
05	May 2015	Sandy Burgess, PharmD	Update per CMS specifications for CY2016 Transition Process
06	May 2016	Sandy Burgess, PharmD	Update per CMS specifications for CY2017 Transition Process
07	May 2017	Sandy Burgess, PharmD	Update per CMS specifications for CY2018 Transition Process
08	May 2018	Sandy Burgess, PharmD	Update per CMS specifications for CY2019 Transition Process
09	May 2019	Sandy Burgess, PharmD Melita Pasagic, PharmD	Update per CMS specifications for CY2020 Transition Process
10	May 2020	Sandy Burgess, PharmD Melita Pasagic, PharmD	Update per CMS specifications for CY2021 Transition Process

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**Attachment 1
PBM POS Transition Flow Diagram**

