POLICY & PROCEDURE

Policy Title:	Pharmacy Benefits Transition Process for Company-Owned Health Plans	Number & Version:	RX53 V.03
Functional Unit:	Pharmacy	Effective Date:	01/01/2024
Policy Owner (Title):	Vice President, Clinical Operations	Page Number:	1 of 10

I. POLICY STATEMENT and PURPOSE

In its administration of Company-owned Medicare Advantage Prescription Drug plan(s), (Health Plan), it is the policy of the Company to contract with an external Pharmacy Benefits Manager (PBM) to administer the Pharmacy Benefits Transition Process. 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 Vice President, Clinical Operations 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

enrollment, beginning on the enrollee's effective date of coverage for the Health Plan 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 PBM 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 Health 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.

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 only apply 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 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.

As outlined in 42 CFR §423.153(b), PBM has implemented Point-of-Sale (POS) PA edits 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 or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) and Cialis drugs as an example).

v. Pharmacy Overrides at Point-Of-Sale: During the member's transition period, all edits (with the exception of those outlined in section III (a)(iv) associated with non-formulary drugs) are automatically overridden at the point-of-sale. Pharmacies can also contact 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, as described further in this policy.

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 a LTC setting.

vi. Transition Fills for New Members in the Retail Setting: The PBM will ensure 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, in which case the Health Plan 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. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [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).

vii. Transition Fills for New Members in the Long-Term Care (LTC) setting: The PBM will ensure:

1. In the LTC setting, 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 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.

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.

4. Emergency supplies and level of care changes for current members: 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 an NCPDP pharmacy submission clarification code. The PBM can also accommodate a one-time fill in these scenarios via a manual override at point of-sale.

   Upon receiving a 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, PBM's claims adjudication system will recognize the current member as 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. <u>Transition Extension</u>

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

c. <u>Six Classes of Clinical Concern</u>

Per CMS guidance, members transitioning to the 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 (PA and/or Step Therapy), 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:

1. Antidepressant;
2. Antipsychotic;

3. Anticonvulsant;
4. Antineoplastic;
5. Antiretroviral; and
6. Immunosuppressant (for prophylaxis of organ transplant rejection).

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 start date with the Plan is provided.

d. <u>Transition Notices</u>

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 Health Plan 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 Health Plan 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 Health Plan and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Health 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.

iv. The Health Plan 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

The PBM will ensure 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 Health Plan must 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 Health 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. The PBM's point-of-sale system is able to accommodate option 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 and the drug is considered a negative change from one plan year to the next. To accomplish this, the system looks back 180 calendar days 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.

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 covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management. The transition across contract year process is applicable to all drugs associated to mid-year and across plan-year negative changes.

iii. 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).

iv. The PBM 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.

g. Public Notice of Transition Process

The Health Plan will make the transition policy available to enrollees via link from the CMS Medicare Prescription Drug Plan Finder site to the Health Plan's web site and include it in pre- and post-enrollment marketing materials, as directed by CMS.

h. Prior Authorization Forms

The Health Plan makes prior authorization and exception 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 Health Plan posts printable and secure online versions of the prior authorization and exception forms on the Health Plan member web site and provider portal.

i. Prior Authorization and Exception Process

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.

When a coverage determination request for a non-formulary drug is received, the plan contacts the prescriber to present formulary alternatives and to obtain a supporting statement indicating that all covered Part D drugs on any tier of the plan's formulary would not be as effective for the enrollee as the requested non-formulary drug, and /or would have adverse effects. If the outcome of the request is unfavorable due to lack of medical necessity, the denial letter that is sent to the member and prescriber lists formulary alternatives for the enrollee's condition.

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 Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance (Effective August 3, 2022)
Medicare Prescription Drug Benefit Manual, Chapter 5 – Benefits and Beneficiary Protections
Medicare Prescription Drug Benefit Manual, Chapter 6 – Part D Drugs and Formulary Requirements

V. RELATED POLICIES / PROCEDURES

None noted

VI. ATTACHMENTS

Attachment – PBM POS Transition Flow Diagram

APPROVALS:

	Printed Name	Signature
Functional Unit Executive:	Jennifer Cruz, PharmD	Jennifer Cruz med
Chief Compliance Officer:	Erin Venable	Erin Venable
Chief Legal Officer:	Gail Halterman	Gail Halterman

VERSION HISTORY:

Version #	Date	Author	Purpose/Summary of Major Changes
01	May 2021	Melita Pasagic, PharmD	This policy has been published under the Lumeris brand since January 2016, as RX03. At this time, a separate policy is created to address nuances in the Essence plan protocols. A Lumeris policy (RX03) on the same subject coexists and is applicable to client plan sponsors' MA-PD plans administered by Lumeris. This policy is updated per CMS specifications for CY2022 Transition Process. The transition flow diagram (Attachment) is updated to reflect current processes. Circumstances related to emergency fills for individuals in LTC are described.
02	May 2022	Melita Pasagic, PharmD	Annual review per CMS specifications for CY2023 Transition Process. Modest updates to clarify. No substantive changes
03	May 2023	Melita Pasagic, PharmD	Annual review per CMS specifications for CY2024 Transition Process. Modest updates to clarify. No substantive changes.

Attachment
PBM POS Transition Flow Diagram