Department: Pharmacy	Version #: 4
Title: Medicare Part D Transition Policy	
Process Owner: Vice President of Pharmacy Operations	Created Date: 05/28/2020 Last Review Date: 02/10/2023
Document Type: Policy	Approver(s): Policy Review Committee
References: Federal Register, Vol. 76, No. 73, Part II, 42 CFR, §423.120(b)(3), §423.153(b), §423.154 Chapter 6 Medicare Prescription Drug Benefit Manual Medicare Marketing Guidelines	Date Approved: 3/9/2023

Printed copies are for reference only. Please refer to the S/Policies and Work Instructions for the most recent version.

Purpose: The purpose of this policy is to describe ATRIO's process for transition 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.

Summary: Transition processes will be administered by ATRIO's Pharmacy Benefits Manager (PBM), MedImpact Healthcare Systems, Inc., in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per 42 CFR §423.120(b)(3).

Scope: This policy is necessary with respect to: (1) new members into prescription drug plans following the annual coordinated election period; (2) newly eligible Medicare members from other coverage; (3) members who switch from one plan to another after the start of a contract year; (4) current members affected by negative formulary changes across contract years; and/or (5) members residing in long-term care (LTC) facilities. This document is intended to describe processes necessary to meet regulatory requirements as of the effective date above.

Definitions:

Term	Description
CMS	Centers for Medicare and Medicaid Services – The agency within the US Federal Government that is charged with the execution and maintenance of the law defining the prescription drug program for senior citizens, the disabled, and the infirm.
Emergency Supply	An Emergency Supply is defined as a one-time transition fill that is necessary with respect to members that are outside of their initial 90-day transition period and that are in the LTC setting.
FTP	File Transfer Protocol – One of the methods used by MedImpact and its clients to transfer electronic files via the Internet. The first two bits of the file indicate the type of file.

HICL	A First Data Bank (FDB) data warehouse term that is an alpha-numeric code used to describe drug ingredients. The HICL codes have been arranged according to an ingredient sequence table. The HICL sequence table establishes relative importance to each ingredient, relative to other ingredients. The relative importance of an ingredient is based on its clinical and therapeutic use. The most important ingredients are sequenced first and the least significant are sequenced last.
Level of Care Changes	Level of care changes include the following changes from one treatment setting to another: • Enter LTC facility from hospitals or other settings; • Leave LTC facility and return to the community; • Discharge from a hospital to a home; • End a skilled nursing facility stay covered under Medicare Part A (including pharmacy charges), and revert to coverage under Part D • Revert from hospice status to standard Medicare Part A and B benefits; and • Discharge from a psychiatric hospital with medication regimens that are highly individualized.
LTC	Long Term Care
MMP	Medicare Medicaid Plans – State level prescription drug plans for Medicare Medicaid eligible participants.
NCPDP	A 7-digit number assigned to a pharmacy by the National Council for Prescription Drug Programs (NCPDP), with the first 2 identifying the state and the last 5 identifying the pharmacy.
NSDE	The FDA's Comprehensive National Drug Code (NDC) Structured Product Labeling Data Elements file. This file is used to provide structured product labeling of Brand and Generic drugs.
PA	Prior Authorization - The process used to make a benefit determination that is made prior to the intended delivery of the healthcare service, treatment or supply under review (e.g., a Pre-Service Claim). Prior Authorization includes requests for coverage determination for medications that are designated on the client Part D formulary as "Prior Authorization Required", "Step Therapy", "Quantity Restrictions" or for requests for exception for non-formulary medications or co-insurance amount
PDE	Prescription Drug Event. File that reports all claims transactions to CMS for inclusion in the annual financial reconciliation between CMS and ATRIO.
POS	The acronym given to MedImpact's point-of-sale prescription transaction processing computer system. Also indicates that the actual retail transaction occurs when the claim is submitted electronically by the pharmacy.
P&T Committee	Pharmacy & Therapeutics Committee – An independent group of external & internal health care practitioners that are responsible for evaluating the efficacy, safety and cost effectiveness of medications to determine potential additions, subtractions and other changes to a formulary.
PBM	Pharmacy Benefit Management or Pharmacy Benefit Manager is a third-party administrator of prescription drug programs for health plans.
UM	Utilization Management – A set of guidelines that are applied independently or jointly in relation to the dispensing or consumption of prescription drugs. The four basic guidelines are prior authorization (PA), quantity limits (QL), step therapy (ST) and tier placement. UM is a tool used by health plans to ensure safe, efficacious and cost-effective use of medication by members.

Policy: ATRIO will ensure that members who are on a drug not on ATRIO's formulary will continue to receive drug coverage through a transition process, receiving a temporary supply of drugs until the member and health care provider can select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity.

1.1 Overview

ATRIO's PBM supports ATRIO in administering a transition process in compliance with the established CMS transition requirements.

This policy is necessary with respect to:

- New enrollees into prescription drug plans following the annual coordinated election period;
- Newly eligible Medicare beneficiaries from other coverage;
- Enrollees who switch from one plan to another after the start of a contract year;
- Current enrollees affected by negative formulary changes across contract years; and
- Enrollees residing in long-term care (LTC) facilities.

ATRIO will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan's formulary and, (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. ATRIO 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. (Attestation 3)

In accordance with CMS requirements, ATRIO will ensure that drugs excluded from Part D coverage are due to the Medicare statute not eligible to be filled through the transition process. However, to the extent that ATRIO covers certain excluded drugs under an enhanced benefit, those drugs will be treated the same as Part D drugs for the purposes of the transition process.

1.2 Transition Population

ATRIO 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 following the annual coordinated election period;
- Newly eligible Medicare beneficiaries from other coverage;
- Enrollees who switch from one plan to another after the start of a contract year;
- Current enrollees affected by negative formulary changes across contract years; and
- Enrollees residing in long-term care (LTC) facilities. (Attestation 1)

1.3 Transition Period

CMS requires a temporary fill of at least a 30-day supply of medication during the first 90 days of the members enrollment. The 90 days are calculated from the plan start date. ATRIO 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. ATRIO has an enhanced transition policy to provide coverage beyond the CMS minimum requirements. (Attestation 13)

ATRIO uses their PBM's default logic to "Transition Across Calendar Years" through the Type 23. The file loads the transition start date default process will run simultaneously and analyze the member's group number assignment and the member's effective date within that plan.

- For members that are new to ATRIO, or for those that are re-enrolling but had a break in coverage, ATRIO's default process will set the transition start date to match the member's effective date.
- For existing (non-new) members that are assigned to a new plan within ATRIO, the default process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or plan assignment.
    - If the change in group number resulted in a new CMS contract assignment, the member's transition start date will be updated to mirror the effective date of the group change.
    - If the change in group number did not result in a new CMS contract assignment, the member's transition start date will remain as is and will not be updated.
    - If the change in group number resulted in a new plan assignment and new formulary ID, the member's transition start date will be updated to mirror the effective date of the group change.
    - If the change in group number did not result in a new plan assignment or new formulary ID, the member's transition start date will remain as is and will not be updated.

ATRIO's default logic aligns with guidance issued by CMS stating plans must effectuate transition for members that change either CMS contract or plan, irrespective of whether or not the change resulted in a new Part D formulary assignment.

CMS believes a minimum of a 108 day look-back (consistent with other reviews) is typically needed to adequately document ongoing drug therapy. While enforcing CMS policy, ATRIO 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. (Attestation 10)

1.4 Implementation Statement

Claims Adjudication System: ATRIO will have systems capabilities that allow ATRIO's 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 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. (Attestation 4)

Pharmacy Notification at Point-of-Sale (POS): ATRIO's PBM utilizes the current NCPDP Telecommunication Standard to provide POS messaging. MedImpact reviews NCPDP reject and approval codes developed during the External Codes List (ECL) process. Pharmacy messages are modified based on industry standards.

c) Edits During Transition: ATRIO 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, edits to help determine Part D coverage (i.e., member level PAs) and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale. (Attestation 8)

ATRIO 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. (Attestation 9)

As outlined in 42 CFR §423.153(b), ATRIO has implemented 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).

d) Pharmacy Overrides at Point-of-Sale (POS): During the member's transition period, all edits (with the exception of those outlined in section 1.4(c)) associated with non-formulary drugs are automatically overridden at the POS. Pharmacies can also contact ATRIO's Pharmacy Help Desk directly for immediate assistance with POS overrides. ATRIO can also accommodate overrides at POS for emergency fills as described in section 1.7. See specific information for the processing of non-formulary drugs in the Six Classes of Clinical Concern section below.

1.5 Transition Fills for New Members in the Outpatient (Retail) Setting

ATRIO will ensure 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 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. 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). (Attestation 5)

1.6 Transition Fills for New Members in the LTC Setting

ATRIO will ensure that 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 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. (Attestation 7)

1.7 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. ATRIO can also accommodate a one-time fill in these scenarios via a manual override at POS.

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 an LTC facility, ATRIO's PBM claims adjudication system will recognize the current member as being eligible to receive transition supplies and will only apply the POS edits described in section 1.4(c) of this policy. In this instance, ATRIO does not need to enter a POS override.

1.8 Transition Across Contract Years

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, ATRIO 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. (Attestation 16)

POS logic is able to accommodate option 1 by allowing current members to access transition supplies at the POS 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, 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 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).

Negative changes are changes to a formulary that result in a potential reduction in benefit to members. These changes can be associated to 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.

1.9 Transition Extension

ATRIO 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, POS overrides can also be entered by ATRIO in order to provide continued coverage of the transition drug(s). (Attestation 15)

1.10 Cost-sharing for Transition Supplies

ATRIO 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, ATRIO 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.
(Attestation 6)

1.11 Six Classes of Clinical Concern

Per CMS transition 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 (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. Anticonvulsants;
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 member start date is provided.

1.12 Member Notification

ATRIO's PBM provides ATRIO (via FTP) with two daily files called the Transition Notification "All" file and the Transition Notification "Print" file. The Transition Notification "All" file, which contains claims data and other member information, provides ATRIO with all of the information needed to contact members and providers regarding transition fills. The Transition Notification "Print" file includes necessary member and claims data needed to produce member notices. This file was created to allow the ability to produce one transition notice per member within a 100 day period where the drug, transition type and applicable drug restrictions are the same.

ATRIO will send written notice consistent with CMS transition requirements, via U.S. first class mail to members within three business days of adjudication of the temporary transition fill. If the member completes his or her transition supply in several fills, ATRIO is required to send notice with the first transition fill only. The notice must include (1) an explanation of the temporary nature of the transition supply a member has received; (2) instructions for working with ATRIO and the member'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 member's right to request a formulary exception; and (4) a description of the procedures for requesting a formulary exception. 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 3 business days after adjudication of

the first temporary fill. ATRIO 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. ATRIO will ensure that reasonable efforts are made to notify prescribers of affected members who receive a transition notice. (Attestation 11)

ATRIO will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to ATRIO web site and include in pre-and post-enrollment marketing materials as directed by CMS. (Attestation 14)

1.13 Provider Notification

ATRIO's PBM provides ATRIO (via FTP) with a file to assist in producing a Prescriber Transition Notification letter to be mailed to the prescriber at the same time the transition letter is mailed to the member. This information is obtained from the existing Transition Notification Files that are sent to ATRIO daily, as described above. The file/letter includes the following:

- Prescriber information
- Member information
- Transition claim details

The letter template provides physicians with formulary alternatives. ATRIO and ATRIO's print vendor adhere to all CMS Marketing Guidelines as set forth in Chapter 2 of the Medicare Prescription Drug Benefit Manual.

1.14 PDE Reporting

Per CMS requirements, 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 PDE.

1.15 CMS Submission

ATRIO will submit a copy of its transition process policy to CMS.

1.16 Pharmacy and Therapeutics Committee Role

ATRIO utilizes ATRIO's PBM's Pharmacy and Therapeutics Committee (P&T) and maintains a role in the transition process in the following areas:

- The PBM's P&T committee reviews and recommends all Part D formulary step therapy and prior authorization guidelines for clinical considerations; and
- The PBM's P&T committee reviews and recommends procedures for medical review of non-formulary drug requests, including the exception process.

1.17 Exception Process

ATRIO follows an overall transition plan for Medicare Part D members; a component of which includes the exception process. ATRIO's exception process integrates with the overall transition plan for these members in the following areas:

- ATRIO'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, ATRIO'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 exception policy includes a process for switching new Medicare Part D plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

ATRIO 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. (Attestation 12)

Resources: WI_Transition Fill Monitoring,