			MA-PD Compliance Policy	
Title:	Transition Process Requirements for Medicare Part D	**Number / Version:**	POL-MA-CO-006	007
Owner Department:	MA-PD Compliance	**Revision Date:**	7/5/2019	
Owner Title:	Director, MA-PD Compliance	**Effective Date:**	01/01/2016	
[reserved]		**Next Review Date:**	5/30/2020	
Affected Departments:	All			

Purpose:

The purpose of this policy is to describe the 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. Transition processes will be administered by the Pharmacy Benefit Manager (PBM) on behalf of Blue-Advantage Plus of Kansas City, Inc. (BA+) in a manner that is timely, accurate and compliant with all relevant Centers for Medicare and Medicaid Services (CMS) guidance and requirements as per 42 CFR §423.120(b)(3).

Scope:

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

Policy:

1.1 Overview

The PBM supports BA+ in administering a transition process that is in compliance with the established CMS transition requirements.

This policy is necessary with respect to:

(1) New enrollees into prescription drug plans following the annual coordinated election period

(2) The transition of newly eligible Medicare beneficiaries from other coverage

(3) The transition of enrollees who switch from one plan to another after the start of a contract year;

(4) The transition of current enrollees affected by negative formulary changes across contract years;

(5) Enrollees residing in long-term care (LTC) facilities.

The PBM 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. The PBM ensures 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.
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.

Also, in accordance with CMS requirements, the PBM 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 BA+ covers certain excluded drugs under an Enhanced benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

1.2 Transition Population

On behalf of BA+, the PBM 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: (1) new enrollees into 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.

1.3 Transition Period

CMS requires a minimum of 90 days from the start of coverage under a new plan. The 90 days are calculated from the plan start date. The PBM will extend its transition policy across contract years should a member enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.

PBM 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.

1.4 Implementation Statement

a) Claims Adjudication System: The PBM has systems capabilities that allow 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 BA+ 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.

b) Pharmacy Notification at Point-Of-Sale (POS): 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.

c) 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, edits to help determine Part D coverage (i.e., member level Prior Authorizations (PA) 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), the 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).

d) Pharmacy Overrides at Point-Of-Sale: 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 point-of-sale. 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 as described in section 1.7.

Please see section 1.11 for specific information for the processing of non-formulary drugs in the Six Classes of Clinical Concern.

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

The PBM 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 BA+ will 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. 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).

1.6 Transition Fills for New Members in the LTC Setting

The PBM 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.

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. The PBM can also accommodate a one-time fill in these scenarios via a manual override at point-of-sale.

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, PBM's claims adjudication 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 1.4(c) of this policy. In this instance, BA+ does not need to enter a point-of-sale override.

1.8 Transition Across Contract Years

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, BA+ 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.

POS logic 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, POS looks for Part D claims in the member's previous 180 days 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

BA+ 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 BA+ or by the PBM (if authorized by BA+ to do so) in order to provide continued coverage of the transition drug(s).

1.10 Cost-sharing for Transition Supplies

On behalf of BA+, the PBM 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, BA+ 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.

1.11 Six Classes of Clinical Concern

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 (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 member start date is provided.

1.12 Member Notification

The PBM provides BA+ (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 BA+ 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.

BA+ will send written notice via U.S. first class mail to enrollee within three business days of adjudication of a temporary transition fill. If the enrollee completes his or her transition supply in several fills, the BA+ 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 an enrollee has received; (2) instructions for working with the plan sponsor 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; 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. BA+ 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.

BA+ will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.

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

1.13 Provider Notification

The PBM provides BA+ (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 BA+ daily, as described above. The file/letter includes the following:

- Prescriber information
- Member information
- Transition claim details

Plans are given the option to use the PBM's preferred print vendor to mail the Prescriber Transition letters or to mail the notification on their own. The PBM has created a Prescriber Transition Notification letter template and a File Specification document for plans to utilize. The letter template provides physicians with formulary alternatives.

1.14 PDE Reporting

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).

1.15 CMS Submission

BA+ will submit a copy of its transition process policy to CMS

1.16 Pharmacy and Therapeutics Committee Role

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

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

1.17 Exception Process

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

1) The PBM'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.
2) When evaluating an exception request for transitioning members, BA+'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.
3) 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.

BA+ 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 BA+ web sites.

Definitions:

Centers for Medicare and Medicaid Services (**CMS) -**– 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 by CMS 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 The PBM and its clients to transfer electronic files via the Internet. The first two bits of the file indicate the type of file.

HICL - An FDB data warehouse term that is an alpha-numeric code used to describe drugs ingredients. The HICL codes have been sequenced 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

NSDE - The FDA's Comprehensive NDC Structured Product Labeling Data Elements file. This file is used to provide structured product labeling of Brand and Generic drugs.

Prior Authorization (PA) - The process undertaken 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.

Prescription Drug Event (PDE) - File that reports all claims transactions to CMS for inclusion in the annual financial reconciliation between CMS and the Plans.

Plan - Medicare Part D Plan Sponsors who are PBM clients.

Point-of-Sale (POS) - The acronym given to the PBM'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.

Policy Administration - The Medicare Advantage and Medicare Prescription Drug Compliance Officer is responsible for the oversight with regard to the performance under this policy.

Regulatory References/Citations:

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
Chapter 3, Medicare Communications and Marketing Guidelines (MCMG)

Accreditation References:

None

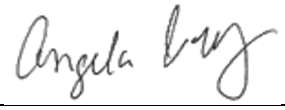
Related Documents:

None

Attachments:

None

Approvals:

Title	Printed Name	Signature	Date
Medicare Advantage Compliance Officer	Angela Muncy		7/5/2019

Version History:

v.##	Date	Owner	Summary of Major Revisions
001	01/01/2016	Medicare Advantage Compliance Officer	Original Version
002	05/28/2016	Medicare Advantage Compliance Officer	Updated verbiage in sections 1.1, 1.2, 1.4, 1.6, 1.8, 1.10 and 1.12
003	06/01/2017	Medicare Advantage Compliance Officer	Updated verbiage in Section 1.11, Updated Attachment 1
004	05/08/2018	Medicare Advantage Compliance Officer	Executive and MACO signatory change.
005	5/9/2019	Medicare Advantage Compliance Officer	Updated template format, updated Regulatory Reference/Citations chapter name, owner elected to have next scheduled review dated as 12/15/2019. Policy ID changed from MAPP-CO-006 to POL-MA-006.
006	5/30/2019	Medicare Advantage Compliance Officer	Updated verbiage in section 1.10 (added 42 CFR in per attestation). Added new PCD transition period language in section 1.11
007	7/5/2019	Medicare Advantage Compliance Officer	Updated 1.1, 1.6 and 1.8 sections to resolve CMS outliers