	POLICY / PROCEDURE	No. PH-917	MSO-PHA-POL-1151-05302024-E
	Transition Process	Effective Date	12/11/2008
		Revision Date	5/16/2025
		Final Approver	**Iris Morant** **VP of Pharmacy**

1.0 Purpose

This policy and procedure outline the MMM Healthcare, LLC process for complying with Medicare Part D transition requirements, including but not limited to, processes for New Enrollees prescribed non-formulary drugs, Current Enrollees affected by negative formulary changes across Contract Years, level of care changes, LTC emergency fills, and transition extension requests.

The purpose of providing a transition supply is to promote continuity of care and avoid interruptions in drug therapy while a switch to a therapeutically equivalent drug or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons can be effectuated.

2.0 Scope

To comply with CMS' requirements and prevent coverage gaps, MMM Healthcare, LLC provides a temporary supply of the requested prescription drug (where not medically contraindicated), which represents ongoing therapy but is non-formulary, and provides Enrollees with notice that they must either switch to a drug on the MMM Healthcare, LLC formulary or request an exception to continue taking the requested drug. The PBM has system capabilities that allow Part D Services 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. MMM Healthcare, LLC has procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new enrollee to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. The coverage determination and medical review process for non-formulary requests are documented in PH-801 Coverage Determination. Also, The PBM transition fill (TF) processing and coding applies point-of-sale (POS) messaging to pharmacies.

This policy and procedure applies to MMM Healthcare, LLC contract numbers:

- MA-PD H4003
- MA-PD H4004
- MA-PD H7522

This transition policy applies 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.

3.0 Policy

MMM Healthcare, LLC and the PBM, are responsible for managing and supporting the Medicare-required transition process for Enrollees who are prescribed Part D drugs that represent ongoing therapy with that drug but are non-formulary, offer an integrated transition solution at the pharmacy point of service (POS) for:

- New Enrollees into prescription drug plans following the annual coordinated election period.
- Newly eligible Medicare Enrollees from other coverage.
- Individuals who switch from one plan to another after the start of a Contract Year. In other words, if an Enrollee disenrolls then re-enrolls in a plan, and has a coverage gap, that enrollee would be eligible for transition.
- Enrollees residing in long-term care (LTC) facilities or Enrollees with level of care changes.
- Enrollees who require a transition extension.
- Current Enrollees affected by negative formulary changes across Contract Years.
- Enrollees affected by a PBM Transition when prior utilization information history is not available.

Biosimilars will be managed as non-interchangeable brand/generic products. For processes involving transition fill, the appropriate cost sharing will apply in accordance with CMS guidance.

4.0 Definitions

Term	Definition
Account Team	The PBM's main points of contact.
PBM	Pharmacy Benefit Manager, Abarca Health.
Annual Notice of Change (ANOC)	The CMS required document that must be sent to all current Enrollees annually in accordance with CMS directions, and that describes changes to existing benefits that are expected for upcoming new Contract Year.
Applicable Month's Supply	CMS required transition supply, as a minimum (unless prescriptions are written for fewer days); the supply is determined as the number of days submitted for the Plan Benefit Package (PBP)'s applicable month's supply submitted to CMS for the relevant plan year. CMS approval determines the approved month's supply for Enrollees in both the non-LTC and LTC settings, Multiple fills up to a total approved month's supply are allowed to accommodate fills for amounts less than prescribed.

Term	Definition
Biosimilar	A biological product submitted to the FDA for approval via the biological abbreviated pathway created by the Affordable Care Act. These products must demonstrate that they are highly similar to the reference (originator) products, i.e.: there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency. Biosimilars have allowable differences because they are made of living organisms.
Current Enrollee	An enrollee that remains on a Part D plan or changes PBP within the same contract, across a Contract Year without any gaps in coverage.
Drug Utilization Review (DUR)	An analysis of prescribed drug usage intended to ensure clinically appropriate drug therapy and quality of patient care; can be conducted concurrently (between the time the prescription is written, and therapy begins), retrospectively (after medication is dispensed), and prospectively (before drugs are prescribed to influence future usage patterns).
Eligibility Data Elements	The elements requested to write rules based on the number of days an enrollee has been enrolled in Part D plan.
Food and Drug Administration (FDA)	The U.S. Food and Drug Administration (FDA) is the government agency responsible for reviewing, approving, and regulating medical products, including pharmaceutical drugs and medical devices.
GPI	Generic Product Indicator categorizes drug products by a hierarchical therapeutic classification scheme. The GPI defines pharmaceutically equivalent drug product that are identical in: active ingredient(s), dose form, route, strength, or concentration.
Low Income Subsidy (LIS)	The program administered by the Social Security Administration (SSA) to subsidize premiums; copayments cost sharing for qualified enrollees (i.e., Extra Help.)
Interchangeable Biological	An interchangeable biological product is biosimilar to an FDA-approved reference product and meets additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the healthcare provider who prescribed the reference product.
Long Term Care (LTC)	A variety of services that help people with health or personal needs and activities of daily living over a period of time. Long-term care can be provided

Term	Definition
	at home, in the community, or in diverse types of facilities including nursing homes and assisted living facilities. Most long-term care is custodial.
LOC	Level of Care (e.g., Inpatient, Outpatient)
MIC	Multi-Ingredient Compound.
MME	Morphine Milligram Equivalent.
NCPDP	National Council for Prescription Drug Programs. This is the non-profit industry standards development organization that develops prevailing Part D claim telecommunications/claims processing standards and guidance.
New Enrollee	New enrollees into Part D plans following the annual coordinated election period, newly eligible Medicare enrollees from other coverage, or individuals who switch from one plan to another plan after the start of the Contract Year.
Non-Long-Term Care (non-LTC)	Describes Retail, Mail and Home Infusion facilities.
NPI	National Provider Identifier.
PAC	Prior Authorization Certification Code. This is a field on the standardized pharmacy adjudication layout for entry of an authorization code provided by the processor.
Part D Drug	Generally, a drug that may be dispensed only upon a prescription that is described in Title XVIII of the Social Security Act.
Patient Location Code (PLC)	Adjudication system values that crosswalk from the Pharmacy Service Type and Patient Residence Type Code.
PBM	Pharmacy Benefits Manager.
P&T Committee	Pharmacy and Therapeutics committee, which is a committee that, among other things, evaluates available evidence regarding the relative safety, efficacy, and effectiveness of prescription drugs within a class of prescription drugs and reviews recommendations for the development of formularies. The committee meets at least quarterly.
PH-801	Coverage Determination Policy and Procedure reference number.
Point of Sale (POS)	A capability of retail pharmacies to electronically access plan design and eligibility information to process and transmit drug claims data at the time of purchase.
Prior Authorization (PA)	An evaluation of the drug's prescribed use against a predetermined set of criteria in order to determine whether the drug/drug class will be covered by the Enrollee's insurance plan.
QL	Quantity Limit

Term	Definition
Submission Clarification Code (SCC)	NCPDP data element indicating that the pharmacist is clarifying the claim submission.
ST	Step Therapy.
Transition Fill (TF)	A temporary supply of a Part D covered drug per CMS Part D requirements.
TF Window	The Enrollee Transition Fill window is the Plan specified number of days (minimum of 90 days) during which Enrollee transition benefits apply.
The Centers for Medicare & Medicaid Services (CMS)	The United States federal agency which administers the Medicare, Medicaid, and the Children's Health Insurance Programs.

Note: The terms enrollee, member, and beneficiary may be used interchangeably across this policy.

5.0 Responsibilities

5.1 MMM Healthcare, LLC ensures the PBM's Account Team has clear understanding of the Plan's transition policy to assure transition policy is set up appropriately within the PBM's system, per each benefit set up and the formulary submitted to CMS by the Plan.

5.2 MMM Healthcare, LLC and PBM thoroughly validate all Part D benefits during a comprehensive iteration testing process which includes validation of the benefit design, formulary, and CMS regulation requirements for new implementations, and all changes to benefits for existing clients, when applicable.

5.3 MMM Healthcare, LLC is responsible for providing a CMS approved letter to be sent to the Enrollee and provider, as specified in this policy.

5.4 The PBM obtains MMM's approved formulary and UM edits and codes it into the adjudication system to identify TF eligible claims at point of sale so that it can be paid.

5.5 The PBM implements edits in the claims adjudication process to enable temporary transition fills for Medicare Part D Eligible drugs. If a claim is approved under transition fill criteria, it includes messaging to the pharmacy

indicating that the claim was paid pursuant to transition fill requirements at the point of sale and a CMS approved letter is sent to the Enrollee and provider as specified in this policy.

5.6 MMM Healthcare, LLC is responsible for making prior authorization, formulary exception request forms, and the plan's transition fill policy available upon request to enrollees, authorized representatives, and prescribing physicians by mail, fax, email, and via the Plan Website.

5.7 MMM Healthcare, LLC is responsible for submitting a copy of the transition policy to CMS and for posting it in its website.

6.0 Procedures:

POS transition supply processing is available and there are procedures in place for transition extensions and overrides, if needed, through the Pharmacy Help Desk. Transition fill POS messaging to pharmacies applies as follows:

a) The PBM's adjudication system automatically processes and pays transition fill-eligible claims and transmits POS messaging indicating these are paid under transition fill rules.
b) Transition fill messaging to pharmacies is consistent with current NCPDP Telecommunication claim standards and include: 1) "Paid under transition fill. Non-formulary"; 2) "Paid under transition fill. Prior authorization (PA) required"; and 3) "Paid under transition fill. Other Reject", which includes step therapy, quantity limit or age edits transition fill reasons. Pharmacies are not required to either submit, or resubmit, a coverage determination request, or other transition fill-specific code for transition fill-eligible claims to pay.
c) Transition fill processing applies to both new and ongoing prescriptions at POS.
d) Communication and educational outreach to network pharmacies is ongoing throughout the year to provide information and instructions regarding transition fill policies and claim processing. At least annually, and more often as needed, transition fill pharmacy communications are distributed by the PBM.
e) Notwithstanding any references in this document to expiring formulary exceptions, since CMS has issued guidance stating that it does not expect Part D plan to include expiring formulary exceptions in their transition policies, MMM Healthcare, LLC and the PBM will not apply its transition policy to expiring formulary exceptions unless and until CMS issues guidance requiring otherwise.

6.1 **Transition Process in the Retail Setting:**

6.1.1 MMM Healthcare, LLC provides one time temporary fill of at least the applicable month's supply (unless the enrollee presents with a prescription written for less than a month's supply in which case MMM Healthcare, LLC 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 the smallest available marketed package exceeds the applicable month's supply, MMM Healthcare, LLC still provides a transition supply when required.

6.1.2 For Enrollees with level of care changes a transition fill may be provided automatically at POS, if the adjudication process indicates a Level of Care change from LTC to non-LTC with an early refill edit. Otherwise, the transition fill is authorized by MMM Healthcare, LLC once the pharmacy identifies that a claim reject is being reflected in the claim adjudication system and that Enrollee's prescription was due to admission or discharge.

6.1.3 The current enrollee transition period covers the period from January 1 to March 31 of the Contract Year, except for new Medicare eligible Enrollees and eligibility changes. During this time, a current Enrollee is provided with a transition supply of an eligible drug anytime there is evidence of prior utilization of the drug within the established look back window of 180 days. Prior utilization is confirmed based on the GPI10 associated with the drug on the incoming claim to any claim that paid for the Enrollee within the same contract for the same GPI10 within the last 180 days. Lacking prior utilization within the look-back window precludes a transition supply from being granted to a current Enrollee during their cross-plan year window.

6.2 **Transition Process in the Long-Term Care (LTC) Setting:**

MMM Healthcare, LLC provides with continued access to transition eligible drugs during their entire 90 days transition window at POS. LTC transition fills are allowed for cumulative applicable month's supply, except for oral brand solids which are limited to 14-day fills with exceptions as required by CMS guidance, unless submitted with a submission clarification code (SCC) of 21-36. SCC codes 21-36 indicate LTC dispensing of varying days' supply. If the Enrollee presents with a prescription written for less than the applicable month's supply, MMM Healthcare, LLC allows multiple fills to provide up to a cumulative of the applicable month's supply of medication to accommodate

fills for amounts less than prescribed during the first 90 days of an Enrollees enrollment is a plan. If the smallest available marketed package sizes do not align with this timeframe, MMM Healthcare, LLC still provides a transition supply when required.

6.2.1 In addition, MMM Healthcare LLC covers an emergency supply of non-formulary drugs for Enrollees in long-term care facilities who are beyond their 90-day transition period to allow requests for formulary exceptions or prior authorization to be processed. In such instances, a minimum of a thirty-one (31) day supply, regardless of dispensing increments, or the prescribed amount of medication, whichever is less, is dispensed. This process is managed by MMM Healthcare, LLC prior authorization advocates.

6.2.2 MMM Healthcare, LLC ensures that Enrollees admitted to/or discharged from an LTC facility, receive a bypass for early refill edits, to guarantee appropriate and necessary access to their Part D benefit. Such enrollees are allowed access to a refill upon admission or discharge.

6.2.3 Cases for Enrollees with level of care changes are also authorized by MMM Healthcare, LLC, in a similar way as for retail setting.

6.3 **Transition process for current Enrollees affected by negative formulary changes in the upcoming year.**

MMM Healthcare, LLC effectuates a meaningful transition by either:

6.3.1 Effectuating a transition prior to the start of the new Contract Year

6.3.1.1 MMM Healthcare, LLC may proactively identify the Enrollees affected by negative formulary changes and grant the authorization (grandfather) of the drug before the start of the new Contract Year, depending on the type of medication therapy, impact on safety to the Enrollee, and Enrollee demonstrated adherence to the therapy, to avoid Enrollee disruption**.**

6.3.2 Or, providing a transition process at the start of the new Contract Year

6.3.2.1 Enrollees that are not grandfathered are notified of negative formulary changes and of the exception process through the Plan's website were formularies are posted and provided a transition fill at the start of the new Contract year, if applicable. For those Employer Health Group Plans that formulary is not posted on the

website, the printed version of the formulary will be provided.

6.3.3 MMM Healthcare, LLC notifies Enrollees with an annual notice of change reflecting negative formulary changes (including step therapy and prior authorization changes) across Contract Years for purposes of determining transition fill eligibility.

6.3.4 MMM Healthcare, LLC designs and executes an annual communication plan with the providers and pharmacies to educate them on the new formulary changes and what are their best alternatives for transition. The plan may include targeted communications to providers with Enrollees impacted by the changes.

6.3.5 When these Enrollees do not switch to the new formulary alternatives, visit a contracted pharmacy, and claim a drug that is no longer on the formulary across Contract Year, the Transition Process in the Retail Setting or LTC Setting section, as explained above, applies.

6.3.6 The current Enrollee transition period covers the period from January 1 to March 31 of the Contract Year, except for new Medicare eligible Enrollees and program eligibility changes.

6.4 **Edits during Transition:**

6.4.1 The PBM implements Drug Utilization Management edits in the claims adjudication system to enable temporary transition fills for Part D drugs. Enrollee eligibility is determined based on Eligibility Data Element. If an Enrollee is not eligible, the claim would not meet transition fill criteria and it would be appropriately rejected. The pharmacy would receive appropriate messaging at the point of sale corresponding to the rejection. If a claim is approved under transition fill criteria, it includes messaging indicating that the claim was paid pursuant to transition fill requirements at the point of sale and a CMS approved letter is sent to the Enrollee and provider as specified in this policy.

6.4.2 Note, however, that transition refills may be rejected or dispensed for less than the prescribed amount for safety reasons including quantity level limits or drug utilization edits based on approved product labeling. In such cases, messaging instructs the pharmacy to lower the quantity and to resubmit the claim using a code for a quantity level limit. The code enables a unique notification to be sent advising the Enrollee of the quantity level limit or drug utilization edit as may be required.

6.4.3 Transition fills proceed for all step therapy and prior authorization edits at point of sale, except for the following utilization edits:

a) Edits to determine Part A or B vs. Part D coverage.
b) Edits to prevent coverage of non-Part D medications (i.e., excluded drugs, OTC)
c) Edits to promote safe utilization of a Part D drugs such as:
   a. an Enrollee-level opioid claim edit.
   b. quantity limits based on FDA maximum recommended daily dose such as APAP.
   c. Early refill edits not a result of a dose change.

6.4.4 For new Enrollees presenting a prescription that represents ongoing therapy for a non-formulary opioid medication or a formulary opioid medication subject to PA or ST under the new plan's utilization management rules, a temporary supply can be provided during transition in accordance with this section, as long as the temporary transition fill does not exceed plan-level limits, cumulative opioid MME edits, or Enrollee-specific limits documented by the previous plan that the current plan also applied.

6.4.5 All edits are subject to exceptions and appeals. MMM Healthcare, LLC's prior authorization, formulary exception request forms, and the plan's transition policy are available upon request to Enrollees, authorized representatives, and prescribing physicians by mail, fax, email, and plan web sites.

6.4.6 MMM Healthcare, LLC 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. If the claim submitted exceeds the quantity limit safety edits or drug utilization edits, this will be managed on a case-by-case basis via a coverage determination, according to PH-801.

6.5 **Transition Timeframes:**

6.5.1 MMM Healthcare, LLC provides a one-time, temporary fill of at least the applicable month's supply of medication (unless the Enrollee presents with a prescription written for less than the applicable month's supply) when an Enrollee presents at a pharmacy to request a refill of a non-formulary drug within the first 90 days of their coverage under the new plan.

6.5.2 MMM Healthcare, LLC provides a temporary supply fill anytime during the first 90 days of enrollment in a plan.

a) For those Enrollees that enroll in the plan at any time during the Contract Year, this requirement applies beginning on the Enrollee's first effective date of coverage, and not only to the first 90 days of the Contract Year.

6.5.3 When going through a PBM claims processing transition or exchange MMM Healthcare, LLC considers all Enrollees eligible for a temporary supply fill anytime during the first 90 days of an Enrollee's enrollment in a plan as defined above.

6.6 **Transition Extensions:**

6.6.1 MMM Healthcare, LLC continues to provide necessary Part D drugs to an Enrollee via an extension of the transition period on a case-by-case basis, to the extent that his or her exception request or appeal has not been processed by the end of the minimum transition period. Continuation of drug coverage will be provided until either a switch to an appropriate formulary drug or a decision on an exception request is made. Procedures are in place for transition extensions and overrides at the POS, if needed, through the Pharmacy Help Desk and Member Services. Pharmacies are not required to either submit, or resubmit, a Prior Authorization Certification Code (PAC), or other transition fill-specific code for transition fill-eligible claims to pay.

6.6.2 MMM Healthcare, LLC extends transition policy across Contract Years should an Enrollee enroll in the plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. These Enrollees are eligible for a TF from the date they enroll in the current Contract Year (i.e., Nov or Dec 1) through the TF Window which starts on January 1 of the next plan year.

6.6.3 MMM Healthcare, LLC gives affected Enrollees guidance regarding how to proceed after a temporary fill is provided, so that an appropriate and meaningful transition can be effectuated by the end of the transition period. Until that transition is made, however, either through a switch to an appropriate formulary drug, or decision of an exception request, continuation of drug coverage will be provided, other than for drugs not covered under Medicare Part D.

6.7 **Brand-new prescription distinction:**

MMM Healthcare, LLC 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 the point-of-sale.

MMM Healthcare, LLC treats new Enrollees that were allowed an initial transition fill for protected class drugs that are subject to PA or ST on new starts only as currently taking the drug. Therefore, any protected class PA or ST requirements for new starts are no longer applicable after the first fill has been provided.

6.8 **Transition Notices:**

6.8.1 The PBM triggers the CMS Model Transition Notice, consistent with CMS transition requirements within three (3) business days from adjudication date to each Enrollee and long-term care Enrollee who receives temporary transition fills. Transition notices to prescribers are generated and mailed when an Enrollee's transition fill notice is produced. The content of this notice is based on the content of the Enrollee transition fill notice, as approved by CMS. Reasonable efforts are made to deliver the notice to the prescriber.

6.8.2 For level of care changes, MMM Healthcare, LLC sends a written notice via U.S. first class mail to each Enrollee who receives transition fills.

6.8.3 The text of the letter to each affected Enrollee follows the model language provided by CMS and includes: (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 (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.

6.8.4 For LTC TF for oral brand solids limited to a 14 day' supply, a TF notice will be sent after the first temporary fill.

6.9 **Cost-Sharing for Transitional Fills:**

6.9.1 For non-LIS Enrollees MMM Healthcare, LLC charges 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 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.

6.9.2 Although LIS does not apply for US territories (P.R.), for LIS Enrollees, the cost sharing for a temporary supply would never exceed the statutory co-payments amount for low-income cost sharing eligible Enrollees.

6.10 **Public Notice of Transition Process:**

6.10.1 MMM Healthcare, LLC makes available to enrollees' general information about the transition process in a manner similar to information provided on formularies and benefit design. The transition process is available in plan pre- and post-enrollment materials.

6.10.2 Enrollees may also view MMM Healthcare, LLC Transition Process via the MMM Healthcare, LLC website link from the Medicare Prescription Drug Plan Finder.

6.11 **Therapeutic Interchange:**

The Medical Director is available to review with the prescribing physician a request for non-formulary drugs, and when appropriate, to define a process for switching enrollees to therapeutic formulary alternatives that fail an affirmative medical necessity coverage determination per PH-801 Coverage Determination.

6.12 **Reject Monitoring:**

On a daily basis MMM Healthcare LLC, validates that all rejects related to non-formulary, prior authorization, step therapy, quantity limits, cost exceeds, NPI and B vs D, issued in the claims adjudication system are appropriate and correct according to the CMS approved formulary. Protected class drugs rejects, and those rejects related to Enrollees in transition are also included within the above

categories. For those that are not appropriate the Plan, makes the necessary efforts to override the affected drug for at least the applicable month's supply and inform the Enrollee about the Coverage Determination process.

6.13 Transition Fill Program Monitoring & Reporting:

The Transition fill process is monitored both across and within each program area that has responsibility for TF processes. TF program monitoring is both quantitative and qualitative.

The PBM utilizes transition claim adjudication data to produce standard paid TF Claim and rejected claim reports for quantitative program monitoring. Program performance monitoring includes reporting and monitoring of all TF types: new and renewing Enrollee TF; and New Patient Admission and LTC Emergency Supply TF. The PBM supports and responds to audits and other data requests, as follows:

a) Audit requests for transition fill data from CMS or other appropriate entities are responded to within the time period designated in the request; or as soon as reasonably feasible, whichever is most appropriate per the requestor.

b) Non-urgent requests for transition fill data are responded to within ten business days. Other response times are available on case-by-case, as needed, basis.

The PBM monitors Transition Fill letters to ensure accuracy and that the content reflects correct information. The PBM also reviews claim reports to flag any rejects that are not getting filled according to the Transition Fill Policy. Transition Fill processing quality checks continue throughout the year in conjunction with routine claim reviews. Weekly and Monthly reports of transition fills and notices are shared with MMM Healthcare, LLC. Should additional ad-hoc reporting be required by CMS, The PBM should develop such reporting.

6.14 P&T Committee Role in Transition:

MMM Healthcare, LLC P&T committee addresses procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new MMM Healthcare, LLC Enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

The P&T committee reviews and provides recommendations regarding the procedures for medical review of non-formulary drug requests.

The P&T committee's involvement helps ensure that transition decisions appropriately address situations involving Enrollees stabilized on drugs that are not on the MMM Healthcare, LLC formulary (or that are on the formulary but require prior authorization or step therapy under utilization management requirements) and which are known to have risks associated with any changes in the prescribed regimen.

7. Implementation Statement:

7.1 The PBM's system capabilities are designed, configured, implemented, and performed in accordance with the Plan's transition policy. The system's capabilities will allow the provision of a temporary supply of non-formulary Part D drug in order to accommodate the immediate needs of the affected enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescribing physician to make an appropriate switch to a therapeutically equivalent medication covered by the plan or the completion of an exception or coverage request to continue receiving coverage for the excluded (or otherwise restricted) drug based on medical necessity reasons.

7.2 The PBM uses the current NCPDP standard D.0 to provide Point-of-Sale (POS) messaging. The NCPDP standard provides information in the response of every transition claim for the system to identify the transition reason. Each reason has a specific NCPDP Code. The PBM has also implemented appropriate system changes to achieve the goals of any modifications or new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim. When a claim is identified as a Transition Fill, an additional message ("Part D Transition Fill") is sent to the pharmacy identifying the claim as a Transition Claim. The additional message sent to the pharmacy is general for all transition fills, independent of its nature.

7.3 Utilization management edits are applied as described below in detail. The PBM will ensure that refills are provided 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.

7.4 The PBM's processing system has functionality to automatically override at POS edits associated with non-formulary drugs (step therapy and prior authorization) and ensure that drug therapies for beneficiaries in transition are not interrupted, as described below.

Implementation Procedures

A. The Temporary Supply in Accordance with MMM Healthcare LLC. Transition Policy (specified at the beneficiary level)

1. Enrollees that are new to the Plan:

   a. Enrollees that are new to the plan and that do not reside in a long-term care facility:

      MMM Healthcare LLC., will cover in the retail setting up to a one-time, temporary supply of at least a month's supply of medication anytime during the enrollee's first 90 days of enrollment in a plan, beginning on the enrollee's effective date of coverage. The temporary supply will be for less days if the prescription is written for fewer days, in which case the plan must allow multiple fills to provide up to a total of a month's supply of medication.

   b. Enrollees that are new to the plan and that reside in a long-term care facility:

      1) Temporary Supply – MMM Healthcare LLC, will cover a temporary supply of at least a month's supply of medication consistent with the applicable dispensing increment in the long-term care setting and given that many LTC pharmacies and facilities must dispense brand name medications in 14-day or less increments. The first supply will be for a maximum of a month's supply (or less if the prescription is written for fewer days, in which case the Plan must allow multiple fills to provide up to a total of a month's supply of medication), as set forth below.

      2) Additional fills – If necessary, MMM Healthcare LLC. will also cover additional refills, up to a month's supply, during the enrollee's first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.

         i. Emergency Supply - After the first 90 days of enrollment, the plan will cover a 31-day emergency supply of the non-formulary Part D drug (or less if the prescription is written for fewer days) in case

the enrollee needs the supply right away and he/she is outside his/her 90-day transition period. This emergency supply is in addition to the supply for the first 90 days of enrollment in the plan and will be approved while an exception or prior authorization is requested.

ii. If approved, the edit will be overridden: LTCES-Allows LTC Emergency Supply.

2. Current enrollees that are not new to plan and whose drugs will be affected by negative formulary changes in the upcoming year; the PBM will make a meaningful transition as explained below.

a. Current enrollees that are not new to the Plan and that do not reside in a long-term care facility:

The Plan covers in the retail setting a one-time, temporary supply of at least a month's supply of medication anytime during the first 90 days of the calendar year, as well as the non-calendar year, (the temporary supply will be for less days if the prescription is written for fewer days).

b. Current enrollees that are not new to the Plan and that reside in a long-term care facility:

The Plan will cover a temporary supply of the drug during the enrollee's first 90 days after enrollment. The first supply will be for a maximum of one month's supply (or less if the prescription is written for fewer days, in which case the Plan must allow multiple fills to provide up to a total of a month's supply of medication). After the first 90 days of the calendar year, the Plan will cover a 31-day emergency supply of the drug (or less if the prescription is written for fewer days) in case the enrollee needs the supply right away and he/she is outside his/her 90-day transition period.

3. Enrollees being admitted to or discharged from a long-term care facility:

   If informed by the Plan, pharmacy, or other mechanism such as documentation at POS, of a level of care change included but not limited to admission or discharge from an LTC facility, the PBM will not use early refill edits to limit appropriate and necessary access to drugs. The PBM or the Plan will override the 'early refill' edit to allow the member to access a refill upon admission or discharge.

4. Enrollees that change treatment settings due to changes in level of care:

   a. In the scenario in which the PBM receives information that an enrollee is changing from one treatment setting to another, for example: hospital discharge to a home, emergency room visit, end of LTC facility, skilled nursing facility (SNF) or hospice stay ("Treatment Setting"), it will be considered a change in level of care. Change in level of care transition supply will not apply to CDT (*Centro de Diagnóstico y Tratamiento*), Policlinics or Medical Groups. The Plan (or PBM on its behalf), will cover a one-time temporary supply of the drug, up to a month's supply of medication (or less days if the prescription is written for fewer days).

      1) Prescriptions received with a header that indicates it is from one of the Treatment settings mentioned will be considered a change in level of care automatically and will be authorized for a one-time temporary supply of the drug.

      2) If a discharge note is received from a treatment setting, such as LTC or SNF, the same procedure will apply. A note will be documented on the patient's record.

   b. In the scenario in which the PBM or MMM Healthcare LLC. receives information that an enrollee is changing from one treatment setting to another and the information specifies that they are requesting a coverage determination, a transition fill will be granted and in addition a Coverage Determination (CD) case will be evaluated.

   c. If MMM Healthcare LLC, does not receive information that evidences a prescription was written incident to or because of a receipt of services from a Treatment Setting, as defined above, the case will be evaluated as coverage determination request. The case will continue nonetheless to be evaluated as a

regular coverage determination and depending on the information necessary to fulfill the CD, it would be approved or denied accordingly.

1) If the claim is for a Conditional Part D drug, which requires a clinical evaluation to determine diagnosis for Part D use, the Coverage Determination personnel should follow the procedures stated in PH-801.

d. If a transition supply for change in level of care applies, the corresponding override will be use depending on the UM in formulary (PA-LOC, PE-LOC, ST-LOC, QL-LOC) and a transition letter will be sent to the beneficiary and the prescriber.

B. Extensions of the Plan Transition Policy:

Once an extension of the transition period is approved, the reject edit will be overridden for both situations:

a. When the 90 days' transition period is completed, the reject will be overridden with the following code: TPE (Transition Period Extension)

b. When the transition period is active but the benefit for a particular medication is completed (a one-time temporary month's supply of medication was already approved and used) the reject will be overridden with the following code: DTPE (Drug with Transition Period Extension)

C. Processing Edits and Transition Fills

1. Drug utilization management edits that are appropriate during a beneficiary's transition period include the following:

   a. Edits to help determine Part A or B vs. Part D coverage,
   b. Edits to prevent coverage of non-Part D drugs (i.e., excluded drugs such as a drug that may be used for sexual dysfunction, or formulary drugs being dispensed for an indication that is not medically accepted), and
   c. Edits to promote safe utilization of a Part D drug (i.e., a beneficiary-level opioid claim edit; quantity limits based on FDA maximum recommended daily dose such as APAP; early refill edits)

1) **Overutilization (Refill too soon):**
   MMM Healthcare LLC., establishes early refill allowance parameters. A hard reject will occur for claims that occur before the threshold has expired. The message indicates the date of the last fill and the Rx number to assist the pharmacy in identifying the previous prescription to make sure that it was correctly paid and consumed by the patient.

2) **Underutilization**:
   Provides a clinical alert in a workflow queue and/or an additional message accompanying a paid or rejected claim when a refill is more than 10 days overdue.

3) **Duplicate therapy:**
   The PBM implements for each client a customized duplicate therapy module that can either be based on the Medi-Span therapeutic duplication database or another level of comparison based on GPI, as preferred by clients. In either case, there can be exceptions of "inclusion" or "exclusion" to the therapeutic duplication rules as established by the client. These rejects can be coded as hard rejects or soft messages per the client's preference.
4) **Drug Disease/Drug Allergy:**
   When the client provides information in the eligibility file relating to allergies that can be appropriately referenced or cross-referenced by the PBM's systems (i.e., Medi-Span allergy codes), a hard reject or message to pharmacy will alert them of a drug-allergy contraindication/issue they may not be aware of.

5) Drug-drug interactions:

The PBM implements, at the client level, a custom drug interaction program (DDIP) that allows the client to define each drug-drug interaction screening program. The PBM Concurrent DDIP programs currently in place for Part D are focused on the most severe type of drug interactions so as not to cause unnecessary delays or impediments in filling a prescription. The program is customized to the desired drug detail level using the GPI code and allows the client to determine whether a hard reject or soft message will be given.

6) Dosage

a) High Dose: Provides a hard reject or soft message, as per client's established parameters, when the number of units prescribed exceeds, the maximum recommended for the age/gender of the beneficiary as per the Medi-Span High Dose and other DUR Modules. The message indicates what the maximum recommended units per day are and instructs the pharmacy to verify the prescription or with the MD and call the plan/PBM for override if appropriate (for a hard reject). Rejections are overridden based on staff pharmacist criteria, with reference to FDA Label or Compendia dosage and administration criteria. Exceptions/modifications to Med-Span thresholds are established on a case-by-case basis when Clinical Staff analyzes rejects and overrides. Clinical staff proactively manages and resolves high dose rejects for protected class medications.

b) Low dose: Provides a message to pharmacy accompanying a paid or rejected claim when daily dose is below Medi-Span low dosing threshold so a pharmacist can verify the prescription.

7) Age/gender-related contraindications

When the client provides information about age and gender in the eligibility file that can be appropriately referenced or cross-referenced by the PBM's systems (i.e., Medi-Span allergy codes), a hard reject or message to pharmacy alerting them of a drug-age or drug-gender contraindication/issue is provided.

8) Clinical abuse/misuse and concurrent fraud, waste, and abuse (FWA) edits

The following edits are available and can either generate a hard edit or an alert message for subsequent verification by plan's staff:

a) Quantity Prescribed is Greater than Quantity Dispensed
b) Different Number of Refills (if the pharmacy increases the total number of refills from the original prescription)
c) High-Cost Dollar Edit (use, thresholds, and design — at Client's discretion— needs to be consistent with CMS guidance as per Client direction)
d) Sanctioned Prescriber (or prescriber under FWA exclusion or investigation)
e) Alerts/Rejects for Network Pharmacy under FWA investigation
f) Package Exceptions for certain types of packages that cannot be subdivided (inhalers, insulin, etc.)

9) Regulatory

a) Validation that Schedule II-V drugs are within the prescriber's scope of practice.
b) For all controlled substances, schedule II-V, the pharmacy is required to enter prescriber DEA license. The PBM's adjudication system confirms the validity of the DEA license. The system also verifies against its database that the specific schedule of the prescribed drug is within the scope of practice of the prescriber's DEA license.
c) Prevention of refills of Schedule II drugs
d) The PBM's adjudication system has POS controls in place to avoid payment of Schedule II drugs refills. Only original claim fill number "0" is adjudicated. Further fills under the same claim are rejected. This control eliminates the risk of having PDEs for Schedule II refills.

10) Conditional Part D drugs

The Plan will apply certain drug utilization management edits, including PA's, during a beneficiary's transition period to prevent Part D coverage for drugs that have a highest likelihood of non-Part D covered uses or to ensure drugs are prescribed for a medically accepted indication. The MMM Healthcare LLC, Coverage Determination Analyst make an appropriate communication outreach to gather the required information (Diagnosis). If met with medically accepted indications the coverage determination is approved. (See Policy PH-801)

2. Generic drugs:

According to the plan's benefit design and CMS regulations, the PBM's adjudication system will apply the programmed rules for the use of generic drugs. Medicare Part D benefit design is not a generic mandatory design.

3. Benefit design:

All rules that have been programmed for the plan's specific benefit design are applied during the processing of a claim during the transition period.

4. **Therapeutic interchange:**

   According to CMS regulation, the plan is required to provide transition supply in the instances described above in policy section.

5. **Quantity Limits Edits:**
   a. Since quantity limit edits are permitted and appropriate during the transition period, 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.
   b. To the extent that a prescription is dispensed for less than the written amount due to a quantity limit safety edit, the PBM provides refills for such transition supply (for at least a month's supply in the outpatient setting and a 31-day supply (with multiple refills) in the long-term care setting).
   c. Beneficiary-level opioid point-of-sale claim edits (and cumulative opioid MED edits) may be applied during transition. If a beneficiary-level POS opioid claim edit has been implemented, during transition, the beneficiary will only receive the opioid dosage that has been determined to be medically necessary and appropriate, based upon the case management process.

6. **Therapeutic Appropriateness edits:**
   Step therapy edits and prior authorization edits:

   The PBM's processing system has functionality that identifies beneficiaries who are eligible to the plan's Transition Policy and automatically overrides step therapy and prior authorization edits or quantity limit edits lower than a beneficiary's current dose during transition for such beneficiaries (with the exception of the edits mentioned above , which are in place to determine Part A or B vs. Part D coverage, prevent coverage of non-Part D drugs, and promote safe utilization of a Part D drug). This functionality bars the possibility of pharmacies making mistakes during transition at point-of-sale which could result in beneficiaries not receiving transition supplies when eligible because of human error. The PBM's processing system thus ensures that drug therapies for beneficiaries in transition are not interrupted due to step therapy and prior authorization edits.

7. Cost-Sharing Considerations under the Transition Policy

a. The Plan must charge cost-sharing for a temporary supply of drugs provided as part of its Transition Policy.

   1. The Plan must charge the same cost-sharing for non-Formulary Part D drugs provided during transition that would apply for non-formulary drugs approved through a formulary exception process.
   2. The Plan must charge the same cost-sharing for formulary drugs subject to utilization management edits during the transition that would apply if the utilization management criteria were met.

b. The cost-sharing for a temporary supply of drugs provided under the Transition Policy will never exceed the statutory maximum co-payment amounts for duals eligible enrollees.

8. Transition Notice

a. The PBM's system issues alerts for the necessity of a written notice to members.

b. MMM Healthcare LLC. through the PBM, provides enrollees an appropriate written notice regarding the transition process upon adjudication of a temporary supply. The system sends a letter to the enrollee explaining the temporary supply for non-Formulary drug coverage (or coverage for a drug which is included on the Plan's Formulary but requires prior authorization, step therapy or other utilization management criteria).

c. The PBM will use the CMS model transition notice to ensure all the Notice requirements in terms of content are met, as provided by plan.

d. The PBM will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive transition notice.

e. Transition Notice should include the following elements:

   1) An explanation of the transition supply's temporary nature.
   2) Instructions for working with the plan and the enrollee's prescribing physician 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 procedure through which a Formulary exception may

be requested.

5) The Plan will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via mail, fax, email, and the plan's website.

f. Once the letter is created and completed, it is saved directly in the PBM's system.

g. The letter is printed and mailed to the enrollee and the prescribing physician daily by the PBM or a contracted entity. The notice is sent via U.S. First Class mail during business days within a timeframe of 3 business days of adjudication of the first temporary transition fill.

h. The transition notice also applies for the first temporary fill of the LTC residents to whom correspond multiples supplies of a Part D drug in multiples of 14-days-or less.

9. Transactional Coding

The PBM is currently using the NCPDP standard D.0. The NCPDP standard provides information in the response of every transition claim for the system to identify the transition reason (Prior Authorization, Non-Formulary, Step Therapy, etc.). Each reason has a specific NCPDP Code. The PBM has also implemented appropriate system changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim.

8.0 Regulatory References:

8.1 Prescription Drug Benefit Manual Chapter 6 ***(Rev. 18, 01-15-16)***
8.2 Part D Formulary Submission and Review CY2026 Training Materials

9.0 Related Policies and Procedures:

9.1 PH 801 Coverage Determinations
9.2 PH 406 Pharmacy and Therapeutic Committee
9.3 PH 802 Exception Process
9.4 CL-TRA-00-001 Part D Transition Process

10.0 Attachments:

N/A

11.0 Document Approvals:

Role	Position	Name of Approver	Approval Signature	Date Approved
	Director of Formulary and Utilization Management	**Maria I. Lázaro;** Pharm.D.	Signatures on File	5/16/2025
	Senior Director, Pharmacy Support	**Jose Mercado Toro**	Signatures on File	5/16/2025
Final Approver	VP of Pharmacy	**Iris Morant Rodriguez; RPh.**	Signatures on File	5/16/2025

12.0 Revision History:

Effective Date	Revision Letter	Document Author	Description of Change
12/11/2008			Initial release.
	07/20/2010	**Nayra Martinez:** Pharm.D.	Policy Revision/Update
	09/28/2010	**Nayra Martinez:** Pharm.D.	Policy Revision/Update
	04/13/2011	**Nayra Martinez:** Pharm.D.	Policy Revision/Update
	06/27/2012	**Nayra Martinez:** Pharm.D.	Policy Revision/Update
	12/20/2013	**Nury Toledo:** Pharm. D.	Policy Revision/Update
	05/28/2014	**Nury Toledo:** Pharm. D.	Policy Revision/Update
	05/28/2015	**Nury Toledo:** Pharm. D.	Policy Revision/Update
	06/01/2015	**Nury Toledo:** Pharm. D.	Policy Revision/Update

	06/01/2016	**Nury Toledo:** Pharm. D.	Policy Revision/Update
	10/03/2016	**Francisco Rivera**: MBA	Policy Revision/Update
	11/30/2016	**Francisco Rivera:** MBA	Policy Revision/Update
	5/23/2017	**Francisco Rivera:** MBA	Policy Revision/Update
	11/14/2017	**Francisco Rivera:** MBA	Policy Revision/Update
	05/24/2018	**Francisco Rivera:** MBA	Policy Revision/Update
	12/13/2018	**Francisco Rivera: MBA**	Policy Revision/Update
	05/24/2019	**Daniel Gali**	Policy Revision/Update
	05/28/2020	**Naytha Lopez**	Policy Revision/Update
	05/26/2021	**Naytha Lopez**	Policy Revision/Update Implementation Statement-6. g. iv; Rejects 75/76 were replaced to reflect reject code 608 to align with NCPCP Standards.
	6/3/2022	**Jonathan Rivera**	Policy Revision/Update
	9/15/2022	**Naytha E. Lopez Otero**	Policy Revision/ Update to Section 4.0, page 4 - New Enrollee Definitions; the word "PBP ID" was changed to indicate "plan"
	5/31/2023	**Naytha E. Lopez Maria Lazaro**	Section 2.0 - Section modified to show the name of new PBM Section 6.1.3; Updated to reflect the change of the lookback period from 365 days to 180 days. Section 6.8.4 - Modified to emphasize that a letter will be sent after each fill, not just with the first

			fill. Implementation statement: Modified to reflect the new PBM process.
	5/30/2024	**Maria Lazaro Jonathan Rivera**	4.0 Definitions; PBM definition added. 6.0 Procedures; b) reference to current version of NCPDP Telecommunication Claim Standards, removed. Reference to quantity limit type, removed. 7. Cost-Sharing Considerations under the Transition Policy. Repetitive paragraph removed.
	5/16/2025	**Maria Lazaro**	Policy Revision/Update