Policy: Part D Transition Policy	Policy Number: RX-01
Department: Pharmacy Operations	**Original Issue Date: 05/16/2022**
Approver: P&T Committee **Date Approved: 7/17/2023**	☒ **Date Last Reviewed / Revised 05/31/2023 OR** ☐ **Date Last Reviewed / No Revisions _____OR** ☐ **New Policy / N/A**
Dependencies: • Mass Advantage Definitions, Abbreviations and Acronyms	**Effective Date: 01/01/2024**

I. PURPOSE

This policy and procedure outlines Central Massachusetts Health's (Mass Advantage's) standard transition logic and how it addresses each Centers for Medicare and Medicaid Services (CMS) requirement.

II. POLICY

Mass Advantage in conjunction with its pharmacy benefit manager (PBM) implements and maintains an appropriate transition process consistent with 42 CFR § 423.120(b)(3) that includes a written description of how, for enrollees who current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for the following beneficiaries:

- New enrollees into Mass Advantage's prescription drug plan 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 the contract year,
- Current enrollees affected by negative formulary changes across contract years, and
- Enrollees residing in long-term care (LTC) facilities.

Annually, Mass Advantage submits a copy of its transition process policy to CMS.

Mass Advantage delegates formulary management to its PBM. Additionally, Mass Advantage ensures that its transition policy applies to non-formulary drugs. For the purposes of transition, non-formulary Part D drugs means the following:

- Part D drugs that are not on Mass Advantage's formulary, and
- Part D drugs that are on Mass Advantage's formulary but require prior authorization (PA) or step therapy (ST) , or that have an approved quantity limit (QL) lower than the enrollee's current dose.

Mass Advantage has processes in place that allow for a medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan beneficiaries to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Mass Advantage via its delegated PBM has system capabilities that can provide a temporary supply of non-formulary Part D drugs in accommodate the immediate needs of an enrollee, as well as to allow Mass Advantage and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the successful completion of an exception request of an existing drug based on medical necessity.

Mass Advantage provides a temporary fill anytime within the first 90 days of an enrollee's enrollment in the plan. However, since certain beneficiaries may join a plan at any time during the year, this requirement applies beginning on the enrollee's first effective date of coverage instead of the first 90 days of the plan year. Because it is possible that the enrollee's drug therapy changed, if an enrollee leaves a plan and re-enrolls during the original 90-day transition period, the transition period begins again with the new effective date of enrollment. However, if there is no gap in coverage, there is no new transition period.

In the retail setting, Mass Advantage provides for a one time temporary fill of at least a month's supply (based on Mass Advantage's approved bid) anytime during the first 90 days of an enrollee's enrollment in a plan, beginning on the enrollee's effective date of coverage. Additionally, if the beneficiary presents a prescription written for less than a month's supply, Mass Advantage allows multiple fills to provide up to a total of a month's supply of medication during the enrollee's transition window. If the smallest available marketed package size exceeds a month's supply, a transition supply is provided as required.

In the LTC setting, Mass Advantage ensures the following:

- The provision of a one-time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should incrementally as applicable under 42 CFR § 423.154 and with multiple fills provided if needed during the first 90 days of an enrollee's enrollment in a plan, beginning on the enrollee's effective date of coverage;
- After the transition period has expired, the provision of at least a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than an applicable month in the LTC setting) while an exception or prior authorization is requested; and
- For beneficiaries being admitted to or discharged from a LTC facility, the provision of a refill upon admission or discharge (i.e., early refill edits are not used to limit medically appropriate and necessary drug therapy).

Mass Advantage's cost-sharing for a temporary supply of drugs provided under its transition process never exceeds the statutory maximum copayment amounts for low-income subsidy (LIS) eligible enrollees.

For non-LIS enrollees, the following cost-sharing applies in transition:

- The cost-sharing for non-formulary Part D drugs provided during transition is the same as that would apply for non-formulary drugs approved through the formulary exception process in accordance with 42 CFR § 423.578(b).
- The cost-sharing for formulary Part D drugs subject to utilization management edits provided during transition is the same as that would apply if the utilization management criteria were met.

Mass Advantage only applies the following utilization management edits during transition at point-of-sale (POS):

- Edits to help determine Part A or B vs Part D coverage;
- Edits to prevent coverage of non-Part D drugs (e.g., statutorily excluded drugs such as a drug used for erectile dysfunction, or formulary drugs being dispensed for an indication that is not medically accepted); and
- Edits to promote safe utilization of a Part D drug (e.g., opioid safety edits, quantity limits based on FDA maximum recommended daily dose such as acetaminophen, early refill edits)

Note: Mass Advantage codes step therapy and prior authorization edits to be resolved at POS.

Mass Advantage's transition process allows for 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. For example, if a beneficiary presents at a retail pharmacy with a prescription for 1 tablet per day for 30 days and Mass Advantage has a quantity limit edit in place that limits the days' supply to 14 per prescription for safety purposes, the beneficiary would receive a 14-day supply (consistent with the safety edit). At the conclusion of the 14-day supply, the beneficiary should be entitled to another 16-day supply while he/she continues to pursue an exception with the Part D plan, or a switch to a therapeutic alternative that is on the plan's formulary.

Mass Advantage applies its transition processes at POS to brand-new prescriptions 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.

Mass Advantage will provide enrollees with appropriate notice regarding their transition process within a reasonable amount of time after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules).

Mass Advantage will send a written notice, via U.S. First Class mail, to each enrollee who receives a transition fill. This notice must be sent to each affected enrollee within 3 business days of adjudication of the temporary transition fill. If the enrollee completes his or her transition supply in several fills, Mass Advantage will send notice with the first transition fill only. This also applies after adjudication of the first temporary fill for LTC residents dispensed multiple supplies in increments of 14-days-or-less. This turnaround is necessary to provide an affected enrollee with sufficient time -- especially considering CMS' 30-day transition fill policy in the retail setting -- to work with his or her prescriber to switch to a therapeutically equivalent drug that is on the plan's formulary or to process an exceptions request.

The notice includes the following elements:

- That the transition supply provided is temporary;
- That the enrollee should work with the sponsor as well as his or her health care provider to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the sponsor's formulary;
- That the enrollee has the right to request a formulary exception, the timeframes for processing the exception, and the enrollee's right to request an appeal if the sponsor issues an unfavorable decision; and
- Mass Advantage's procedures for requesting a formulary exception.

Mass Advantage utilizes the National Council for Prescription Drug Programs (NCPDP) work-around process for using structured payment coding in the message field of billing transaction responses indicating that a particular fill is a transition supply. This process is consistent with the current NCPDP standard.

Mass Advantage makes available prior authorization or exceptions request forms upon request from enrollees or prescribers via mail, fax, email, and on the Mass Advantage web site. These forms are available as a link from the Pharmacy Benefits page on the Mass Advantage website.

Mass Advantage extends its transition policy across contract years should an enrollee have an effective enrollment date of either November 1 or December 1 and need access to transition supply.

Mass Advantage makes its transition process available in plan pre- and post-enrollment materials and its website under the Pharmacy Benefits section for enrollee and public review. There is also a link from the Medicare Plan Finder to Mass Advantage's web site. This assures beneficiaries there will be procedures in place to assist them in switching to therapeutic alternatives or in obtaining a formulary exception where appropriate when switching plans or switching medications at the start of a plan year.

Mass Advantage 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 text 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).

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, Mass Advantage will effectuate a meaningful transition by either:

- Providing a transition process at the start of the new contract year or
- Effectuating a transition prior to the start of the new contract year.

Transition eligible codes may be sent to the pharmacy for a transition fill. The pharmacist, depending on the code as with all claims, may be able to resolve at point-of-sale, or may need to call the pharmacy help desk to get assistance with how to get the claim processed if it is eligible for a transition fill. These claims are monitored daily through the rejected claims reporting to ensure that the rejections are appropriate. If the claim processes without an error code, the pharmacist will fill the prescription.

III. DEFINITIONS

A. **Applicable Month's Supply:** Refers to CMS' required transition supply. This amount is determined by the CMS approved number of days (non-LTC and LTC) submitted for the Plan Benefit Package's (PBP) for the relevant plan year.

B. **Centers for Medicare & Medicaid Services (CMS)**: Refers to the federal agency within the United States Department of Health and Human Services that administers the Medicare program.

C. **Contract Year**: Refers to the period for which a particular PBP applies.

D. **Enrollee**: Refers to an individual enrolled in one of Mass Advantage's Medicare Part D plans, also known as a beneficiary or member.

E. **Food and Drug Administration (FDA)**: Refers to the federal agency within the United States Department of Health and Human Services that is responsible for regulating foods, drugs, biologics, medical devices, electronic products that give off radiation, cosmetics, veterinary products, and tobacco products.

F. **Long-Term Care (LTC) Facility**: Refers to facilities or institutions, such as nursing homes, that provider healthcare to beneficiaries who are unable to manage tasks known as activities of daily living.

G. **Low Income Subsidy (LIS)**: Refers to subsidized premiums, deductibles and/or copayments for which some Medicare beneficiaries are eligible. This is also known as Extra Help.

H. **Medicare Part D (Part D)**: Refers to the Medicare prescription drug benefit.

I. **Medicare Part D Drug**: Refers to a drug that is used for a medically-accepted indication and is included in one of the following categories: (1) A drug that may be dispensed only upon a prescription that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; (2) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; (3) Insulin described in section 1927(k)(2)(C) of the Act; (4) Medical supplies associated with the delivery of insulin; and (5) A vaccine licensed under section 351 of the Public Health Service Act and its administration.

J. **Morphine Milligram Equivalent (MME)**: Refers to the potency of an opioid relative to morphine.

K. **National Council of Prescription Drug Benefit Programs (NCPDP)**: Refers to the American National Standards Institute (ANSI) accredited standards developing organization, that is responsible for the development and maintenance of the following standards: telecommunications standard, SCRIPT standard used to transmit electronic prescription, eligibility and benefit standard, and formulary and formulary and benefit standard.

L. **National Drug Code (NDC)**: Refers to the three-segment number used by the FDA to identify drugs.

M. **Non-formulary Drug**: For the purposes of transition, refers to (1) Part D drugs that are not on a sponsor's formulary, (2) drugs previously approved for coverage under an exception once the exception expires, and (3) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy, or that have an approved quantity limit lower than the enrollee's current dose, under a plan's utilization management requirements.

N. **Pharmacy Benefit Manager (PBM)**: Refers to a company that manages prescription drug benefits for a health plan.

O. **Prior Authorization (PA)**: Refers to a utilization management strategy in which a formulary medication will not covered unless pre-established criteria have been met.

P. **Protected Class Drug (PCD)**: Refers to a drug in one of the following classes: immunosuppressants for prophylaxis of organ rejection, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics.

Q. **Quantity Limit (QL)**: Refers to the utilization management strategy in which the amount of drugs that can be dispensed in a single transaction at point-of-sale. Quantity limits are either approved by CMS or are based on the FDA's maximum daily dose limits.

R. **Step Therapy (ST)**: Refers to the utilization management requirement to try a less costly but just as effective drug before the plan covers another drug.

S. **Submission Clarification Code**: Refers to a code added to a claim before submission that provide the payer with additional details about the dispensing.

T. **Transition Fill**: Refers to the temporary fill of medication for new enrollees or continuing enrollee who experience a negative change. This fill is provided within the first 90 days of an enrollee's eligibility. The purpose of a transition fill is to promote continuity of care and to avoid disruptions in therapy while the enrollee switches to a therapeutically equivalent drug or while the enrollee seeks an exception.

IV. References

- 42 CFR **§** 423.120(b)(3) Transition Process
- Annual Medicare Part D Model Transition Notice **https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials**
- Health Plan Management System (HPMS) Formulary Submission Module & Reports Technical Manual (May 2023)
- Health Plan Management System (HPMS) Memo: Annual Part D Formulary Submission Information
- Medicare Prescription Drug Benefit Manual Chapter 6 Part D Drugs and Formulary Requirements (Rev. 18, 01-15-2016)

MASS ADVANTAGE

V. Version & Review History:

Version #	Action (Original Issue, Reviewed, Revised)	Date Action Taken	Brief Summary of Revision, if applicable	Individual Taking Action	Effective Date	Date Approved and By Whom
1	Original Issue	06/02/2022	Policy Origination	Susan Jones	01/01/2023	P&T Committee 05/16/2022
2	Reviewed and Revised	05/31/2023	Minor grammatical corrections	Erica Hursey	01/01/2024	P&T Committee 07/17/2023