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1.0 PURPOSE

- 1.1 To describe the Company’s transition process and how it addresses situations in which an individual first presents at a participating pharmacy with a prescription for a drug that is not on the formulary, unaware of what is covered, or unaware of the exception or prior authorization, step therapy process to provide access to Part D drugs.

2.0 SCOPE

- 2.1 The Company will maintain an appropriate transition process, consistent with 42 CFR §423.120(b)(3), Chapter 6 of the *Medicare Prescription Drug Benefit Manual* and any other CMS guidance, 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.

3.0 ACCOUNTABILITY

- 3.1 It is the responsibility of the Senior Vice President of Government Programs to oversee overall compliance with this procedure.
- 3.2 It is the responsibility of the department Managers to:
 - 3.2.1 Ensure development, implementation, and ongoing evaluation of this procedure.
 - 3.2.2 Ensure staff training and compliance with this procedure.
 - 3.2.3 Manage the publication and approval of this procedure to the Doc Control Repository.
- 3.3 It is the responsibility of the staff to:
 - 3.3.1 Carry out and utilize all relevant policies, procedures, work instructions and other documentation to facilitate the efficient operation of the assigned task(s).

4.0 DEFINITIONS

- 4.1 ANOC: Annual Notice of Change.

- 4.2 Clients: Entities that are contracted with Company to offer pharmacy benefit management services.
- 4.3 CMS: Centers for Medicare & Medicaid Services.
- 4.4 Company: Optum and its subsidiaries and affiliates.
- 4.5 Emergency Fill: After the initial new-enrollee transition period and initial 108-day formulary change across contract year period, LTC facility residents who are ordered non-formulary, PA, ST drugs, must receive their medications as ordered without delay. Therefore, Part D plans must cover an emergency supply of these drugs for LTC facility residents as part of their transition process. These emergency supplies of non-formulary Part D drugs, including Part D drugs that are on a sponsor's formulary but require PA or ST under a sponsor's utilization management rules, must be for at least 31 days of medication. If the prescription is written by a prescriber for less than 31 days, multiple fills must be allowed for up to 31 days' supply.
- 4.6 Enrollee: Member of a client plan to which Company provides pharmacy benefit management services.
- 4.7 EOB: Explanation of Benefits.
- 4.8 FDA: Food and Drug Administration
- 4.9 Formulary: Entire list of Part D drugs and their proper dosage that CMS would cover on a PDP or an MA-PD that is included with a given plan for a client. Continually updated list of medications, related products, and information representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health. Types include closed formulary, incentive formulary, and open formulary. Also, a status used to indicate that the drug is covered by the benefit plan.
- 4.10 Formulary Changes Across Contract Years: Includes drugs that will become non-formulary (no longer covered on the formulary), or drugs that remain on the formulary but have new PA or ST restriction(s) added from one contract year to another (negative change).
- 4.11 GUI: Graphical User Interface. Application that drives variable information that appears on transition notices. This Interface is only used for certain system platforms and may not be applicable for all clients.
- 4.12 HIPAA: Health Insurance Portability and Accountability Act of 1996, as amended periodically.
- 4.13 HPMS: Health Plan Management System. Web-based platform for submission to CMS of Medicare Part D formularies and formulary updates.
- 4.14 ITU Pharmacy: Indian Health Tribal and Urban Pharmacy. Pharmacy operated by the Indian Health Service (IHS), an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in Section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.
- 4.15 Level-of-Care Change: When an enrollee is changing from one treatment setting to another. Examples include, but are not limited to: (1) beneficiaries who enter LTC facilities from hospitals; (2) beneficiaries who are discharged from a hospital to a home; (3) beneficiaries who end their Medicare Part A skilled nursing facility stay (where payments include all pharmacy charges) and who need to revert to their Part D

plan formulary; (4) beneficiaries who give up hospice status to revert to standard Medicare Part A and B benefits; (5) beneficiaries who end an LTC facility stay and return to the community; and (6) beneficiaries who are discharged from psychiatric hospitals with drug regimens that are highly individualized. Within adjudication system, level-of-care change has been identified based on Patient Residence Code (vD.0 format) change.

- 4.16 LIS: Low-Income Subsidy.
- 4.17 LTC Facility: Long-Term Care Facility. Facility that provides rehabilitative, restorative, and/or ongoing nursing care to patients or residents in need of assistance with activities of daily living.
- 4.18 MADD: Maximum Allowable Daily Dose.
- 4.19 Medicare Part D Excluded Drugs: Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B, even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B. Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) or (d)(3) of the Social Security Act, except for smoking cessation agents.
- 4.20 Medicare Part D Plan (Part D Plan): Prescription Drug Plan (PDP), Medicare Advantage Prescription Drug Plan (MA- PD), Program of All-Inclusive Care for the Elderly (PACE) Plan offering qualified prescription drug coverage, or a Cost Plan offering qualified prescription drug coverage.
- 4.21 NCOA: National Change of Address database; the NCOA process consists of computer software purchased, leased, or developed by the Company to access the NCOA database. The U.S. Postal Service certifies the process and licenses the NCOA product to private sector companies for commercial mail list processing or internal mail list management.
- 4.22 NCPDP: National Council of Prescription Drug Programs. Not-for-profit ANSI-Accredited Standards Development Organization representing virtually every sector of the pharmacy services industry that creates standards used for claims adjudication.
- 4.23 Network Pharmacy: Licensed pharmacy under contract with a Part D plan to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.
- 4.24 Non-Formulary Drug: CMS defines Non-Formulary drugs to mean: 1) Part D drug that is not on a Medicare Part D plan's formulary. A non-formulary drug may include a medication that was covered under the enrollee's prior plan but is not on the Medicare Part D formulary for the plan (i.e., non-covered Part D medication). 2) Part D drugs that are on a Medicare Part D plan's formulary but require prior authorization or step therapy, or that have an approved formulary QL lower than the beneficiary's current dose, under a plan's utilization management requirements. This is because a formulary drug that is restricted via UM requirements is essentially equivalent to a non-formulary Part D drug to the extent that the associated UM requirements are not met for a specific beneficiary. However, this definition does not apply to safety QLs, which are equal to an FDA maximum dose limit, or UM intended to prevent unsafe use of a medication consistent with FDA labeling, or UM to validate the Part D eligibility of a drug. The Company will apply all transition processes to brand-new prescriptions for a non-formulary drug if it cannot make the distinction between a new prescription and an ongoing prescription at the point of sale.

- 4.25 P&T Committee: Pharmacy and Therapeutics Committee.
- 4.26 Part D Drug:
- 4.26.1 Defined in Title XVIII of the Social Security Act (the Act) and in the regulations (42 CFR 423.100).
 - 4.26.2 Any of the following if used for a medically accepted indication (as defined in section 1860D-2(e)(4) of the Act):
 - A. A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act
 - B. A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act
 - C. Insulin described in section 1927(k)(2)(C) of the Act
 - D. Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze; (v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration
 - E. Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation
 - F. A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in paragraphs (1)(i), (ii), (iii), or (v) of this definition.
 - 4.26.3 A Part D drug does NOT include any of the following:
 - A. Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B)
 - B. Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.
 - C. Medical foods, defined as a food that is formulated to be consumed or administered internally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.
- 4.27 Participating Pharmacy: Licensed pharmacy under contract with a Part D plan to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.
- 4.28 POS: Point-of-Sale.
- 4.29 PA: Prior Authorization.
- 4.30 PBP: Plan Benefit Package.
- 4.31 Prior Authorization, Step Therapy Transition Codes: Two-letter codes used to specify the type of transition fill.

- 4.32 QL: Quantity Limit.
- 4.33 SNF: Skilled Nursing Facility. Establishment that houses chronically ill (typically elderly patients) and provides long- term nursing care, rehabilitation, and otherservices.
- 4.34 SME: Subject Matter Expert. Individual with an in-depth knowledge of a specific business area that enhances Company performance due to their ability to assist with complex issues based on their depth of understanding of subject matter relative to their area of expertise.
- 4.35 ST: Step Therapy
- 4.36 Transition: Includes (1) transition of new enrollees into a Medicare Part D plan; (2) transition of newly eligible enrollees into a Medicare Part D plan from other coverage; (3) transition of enrollees from one plan to another after the start of a plan year (i.e., after January 1); (4) movement of enrollees in or out of an LTC facility; or (5) current enrollees in a Medicare Part D plan affected by fomulary changes from one plan year to the next. Copayment and cost-sharing for transition claims are processed in accordance with the enrollee's full benefit design. Company extends its transition process across contract years should an enrollee enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.
- 4.37 Transition Notice: Written notice mailed to enrollee following receipt of a temporary fill during the transition period. The notice is in accordance with CMS guidance and contains the following information: (1) an explanation of the temporary transition supply enrollee has received during transition period; (2) instructions for working with the Company and enrollee's prescriber to identify appropriate therapeutic alternatives that are on the Medicare Part D plan's fomulary or exception request forms (available to enrollee via USPS mail, web site, or facsimile) for fomulary drugs that need PA, ST, or QL; (3) explanation of enrollee's right to request an exception; and (4) description of procedure for requesting an exception. Per CMS requirements, each Medicare Part D plan is responsible for obtaining CMS approval of the transition notice.
- 4.38 Transition Period: First 108 days of coverage under a Medicare Part D plan following a transition. During this time, Medicare Part D plans must provide a temporary fill of a non-fomulary drug or drug on fomulary with a PA, ST, or QL. CMS auditors are using a 108-day lookback period to establish ongoing therapy as their guideline for reviewing transition claims. Therefore, the Company standard for the transition window is 108 days, instead of 90 days.
- 4.39 UM: Utilization Management.

5.0 PROCEDURES

5.1 SUBMISSION OF POLICY

- 5.1.1 The Company provides a copy of this Transition Process policy to the plan sponsor on an annual basis.
- 5.1.2 This policy is to have been reviewed and approved by the Company's P&T Committee, business process owners, and SMEs.
- 5.1.3 The plan sponsor is then responsible for additional custom language applied to the specific Contract/PBP, P&T reviews, and submission to CMS, or to provide CMS their own Transition Process policy for review and approval.

- 5.1.4 The plan sponsor is also responsible for making the Transition Process policy available to Medicare beneficiaries in post-enrollment marketing materials.
- 5.1.5 The Company monitors CMS guidance for any necessary updates or revisions to current policy.

5.2 TRANSITION SUPPLY FOR NON-FORMULARY DRUGS

The Company has system capabilities that allow a temporary supply of non-formulary Part D drugs in order to accommodate immediate needs of an enrollee, as well as to allow the plan and/or 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.

- 5.2.1 The Company's Transition Process policy applies to drug claims, including compound claims, that fall under the following definitions, meaning both:
 - A. Part D drugs that are non-formulary
 - B. 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 UM rules.
- 5.2.2 The Company's 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. A member must meet appropriate medical necessity and coverage criteria before a non-formulary exception request will be approved. Lack of medical necessity may result in member switching to therapeutically appropriate formulary alternatives through the non-formulary exception process as described in the Medicare Prescription Drug Benefit Manual, Parts C & D Enrollee Grievances, Coverage Organization/Coverage Determinations, and Appeals Guidance.
 - A. To determine medical necessity, the Company verifies through the prescriber's supporting statement and/or standards, documented in clinical guidelines adopted by the plan/client, that the requested prescription drug is medically necessary to treat the member's disease or medical condition and meets one of the following three criteria:
 - 1) Other formulary or covered drugs on any tier of the plan/client's formulary would not be as effective for the member as the non-formulary drugs and/or the other drugs would have adverse effects; or
 - 2) No other formulary or covered drugs on any tier of the plan/client's formulary would be as effective for the member as the non-formulary drugs and/or the other drugs would have adverse effects; or
 - 3) The formulary or covered alternative has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the member.
 - B. Enrollees and physicians may obtain forms to arrange for an exception of non-formulary drugs through a variety of means, including mail, fax, email, and their Medicare Part D plan sponsor's website. Although these forms are not required, they are helpful for the evaluation of the requests.
 - C. Actions taken when a transition claim pays:
 - 1) If necessary, a transition letter is provided to both the member and prescriber which describes the coverage determination process
 - 2) The prescriber can review the letter and suggest therapeutically appropriate formulary alternatives for the member and prescribe agreed-upon therapeutically appropriate formulary alternative

- 3) If no formulary alternatives are appropriate for the member's needs, the prescriber or the member can initiate a prior authorization or exception (coverage determination) request.
- 4) Members are notified of their appeal rights when medical necessity coverage determinations result in a denial decision.
- 5) If the prior authorization or exception is denied, an appeal (redetermination) request can be initiated and expeditiously processed upon request.

5.3 TRANSITION SUPPLY FOR DRUGS WITH UM CONTROLS

- 5.3.1 The Company's Transition Process policy also applies to Part D drugs that are on a plan's formulary but require PA, ST, or QL under a plan's UM rules. Step therapy and prior authorization edits are resolved at point-of-sale through paid transition claims.
- A. The Company applies the following UM edits during transition at POS:
- 1) Edits to determine Part A or B vs. Part D coverage
 - 2) Edits to prevent coverage of non-Part D drugs
 - 3) Edits to promote safe utilization of a Part D drug
- 5.3.2 The Company has also established medical review and coverage determination processes to evaluate the medical necessity of PA, ST, QL and non-formulary drug requests and to provide authorizations or therapeutic formulary alternatives when medical necessity is not affirmed (Refer to section 5.2.2).

5.4 TRANSITION FOR NEWLY IMPLEMENTED UM CONTROLS

- 5.4.1 For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Company effectuates a meaningful transition by either:
- A. Providing transition procedures consistent with transition process required for new enrollees at the start of a new contract year, or
- B. Effectuating a transition prior to the start of the new contract year
- 5.4.2 The plan sponsor provides instructions to the Company regarding which approach they will take for a meaningful transition.

5.5 RETAIL SETTING - TEMPORARY FILL AMOUNT

- 5.5.1 The Company ensures that in the retail setting, the Transition Process policy provides for at least a one-time, temporary month's supply (depending on client's instructions), unless the enrollee presents with a prescription written for less than a month's supply, in which case the Company must allow multiple fills to provide a total of a month's supply medication. The Company also allows appropriate transition fills for drugs manufactured in "unbreakable packages."
- 5.5.2 This may occur anytime during the first 108 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.
- 5.5.3 If applicable, the Company provides a transition fill for current enrollees within the first 108 days of the plan year under "Formulary Change across Contract Year" transition rules.

5.6 COST-SHARING ON TEMPORARY FILLS

- 5.6.1 The Company charges cost-sharing for a temporary supply of drugs provided under the transition process, subject to the following guidelines:
- A. Cost-sharing for transition supplies for LIS-eligible enrollees never exceeds statutory maximum copayment amounts.

- B. For non-LIS enrollees, charges for cost-sharing for non-formulary drugs is based on one of the client's approved drug cost-sharing tiers, and this cost-sharing is consistent with cost-sharing that is charged for non-formulary drugs approved under a coverage exception.
- C. For non-LIS enrollees, cost-sharing for formulary drugs with UM waived for transition supply is based on the applicable formulary tier had the UM not been waived for transition.
- D. Cost-sharing for drugs provided under the transition process will never exceed the statutory maximum co-payment amounts as specified by the Inflation Reduction Act for products containing insulin or ACIP recommended Part D eligible vaccines.

5.7 TRANSITION FOR LTC SETTING

5.7.1 The Company ensures that in the LTC setting:

- A. The Transition Process policy provides for a month's supply fill consistent with dispensing increment requirements, with refills provided if needed, during the first 108 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.
- B. After the transition period has expired, the Transition Process policy provides for a 31-day emergency supply of non-formulary Part D drugs consistent with dispensing requirements while an exception or PA is requested.
- C. For enrollees being admitted to or discharged from an 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.
- D. LTC enrollees are identified based on patient residence codes submitted on claim(s). This indicator permits a refill of a month's supply of transition medication.

5.8 LEVEL-OF-CARE CHANGES

The Company provides transition fills for enrollees who experience a transition characterized as a level-of-care change from one treatment setting to another.

5.8.1 Examples of level-of-care changes where a transition may apply include:

- A. Enrollees who are discharged from a hospital to a home setting (i.e., assisted living, LTC, or private home) accompanied by a list of medications that may not always consider the formulary of the enrollee's plan due to the short-term nature of the hospital visit
- B. Enrollees who end their SNF Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary
- C. Enrollees who give up hospice status to revert to standard Medicare Part A and B benefits
- D. Enrollees who end an LTC facility stay and return to the community
- E. Enrollees who are discharged from psychiatric hospitals with drug regimens that are highly individualized

5.8.2 The Company considers these unplanned transitions and applies the transition fill process as required.

5.8.3 Company understands that while Part A provides reimbursement for "a limited supply" to facilitate enrollee discharge, the enrollee is entitled to a full outpatient supply in order to continue therapy once this limited supply is exhausted. This is particularly true for enrollees using a mail-order pharmacy or home infusion therapy, or for those residing in rural areas where obtaining a continuing supply of drugs may involve certain delays.

5.8.4 The Company allows that enrollees are able to receive their outpatient Part D prescriptions upon discharge from a Part A stay through this transition process.

5.9 ONE-TIME FILLS FOR UNPLANNED TRANSITION FROM HOSPITAL, LTC, SNF, OR HOSPICE

For an enrollee leaving a hospital, SNF, or hospice setting (where prescriptions are covered under Medicare Part A or Part B), the discharge list of prescription orders may contain medications that are either non-formulary or subject to UM edits. (Please refer to the “Level-of-Care Change” definition to review additional examples of level-of-care changes.

- 5.9.1 It is the policy of OptumRx to automate the identification of level-of-care changes based on a change in patient residence code. When a level-of-care change is identified, the system will automatically override rejections included but not limited to Refill-too-Soon, Non-formulary and UM edits.
- 5.9.2 If the member did not have a change identified by a change in patient residence code, in order to ensure that the enrollee does not have a gap in therapy, the pharmacist should call the Pharmacy Help Desk to notify them of the level-of-care change in order to have an authorization placed in the system allowing the claim to pay.
- 5.9.3 This authorization is to address the above edits, resulting in a paid claim as determined by the plan.
- 5.9.4 These authorizations are to be entered as one-time authorizations; however, if the member has subsequent level-of-care changes, additional one-time authorizations are to be entered to ensure there are no gaps in therapy.
- 5.9.5 Enrollees are provided with appropriate written transition letter notification regarding their transition supply for any of the reasons indicated in the CMS model transition notice. This notice includes an explanation of the temporary nature of the transition supply, along with instructions for working with the plan and enrollee's prescriber to determine an appropriate therapeutic formulary alternative.
- 5.9.6 Additionally, the letter template provides an explanation on enrollee's right to request a formulary exception with procedures on how to pursue that option.
- 5.9.7 One transition letter is generated per claim, even when multiple UM restrictions have been waived. For example, if the drug has exceeded both PA and QL restrictions, one letter is sent and includes both reasons.
- 5.9.8 If a member receives multiple transition fills of different drugs on the same day, a letter is to be generated for each drug.
- 5.9.9 At least annually, the Company pharmacy network is to be reminded of clarification codes to submit for these situations via faxblast from the Provider Relations Department.

5.10 QUANTITY LIMITS, REFILL-TOO-SOON, AND SAFETY EDITS

The Company's Transition Process policy provides for refills of transition prescriptions dispensed for less than written amount due to QLs for safety purposes or drug utilization edits that are based on approved product labeling.

- 5.10.1 The Company only applies certain drug UM edits during a beneficiary's transition period at POS.
- 5.10.2 Drug utilization management edits that are appropriate during this transition period include: edits to help determine Part A or B vs. Part D coverage; edits to prevent coverage of non-Part D drugs (i.e., excluded drugs); or edits to promote safe utilization of Part D drugs (i.e., MADD edits based on FDA maximum recommended doses, early refill edits); or edits to maximize appropriate dose.
- 5.10.3 The Company applies edits to certain non-six clinical class drugs, MADD edits, B vs. D administrative PA edits, and early refill edits during transition. Resolution of edits is made by the dispensing pharmacist at POS by either: (1) resubmitting claim with revised/corrected information, or (2) calling the Member Services Department/Pharmacy Help Desk. Edits that are placed on the formulary vary by formulary (CMS-approved) and client benefit design.
- 5.10.4 Edits applied during transition are managed and resolved through POS and review activity.
- 5.10.5 If any non-formulary, PA, ST, or QL edit is overridden at POS for transition purposes only, but not permanently, the Company notifies the beneficiary so that s/he can begin the exception process, if necessary. Notification occurs via U.S. first-class mail to the enrollee within three (3) business days of adjudication of a temporary fill. Notification specifics are outlined under "Transition Notification" section.
- 5.10.6 All non-formulary, PA, and ST edits are subject to exception request and appeal. The Company ensures beneficiaries are made aware of any edits that result in a prescription being filled differently than originally written, as well as their right to request an exception.
- 5.10.7 The Company expeditiously processes such exception requests so that beneficiaries do not experience unintended interruptions in medically necessary Part D drug therapies and/or inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.
 - A. All non-formulary, PA, ST, or QL edits (not including Part B vs. Part D or Part D vs. Part D-excluded prior authorizations, edits to reject non-part D drugs, QLs for safety reasons, and early refill edits) are overridden during the transition period to allow multiple fills up to the overall transition days' supply limit. Multiple refills of a transition supply may therefore be obtained up to the maximum allowable days' supply of a transition supply.
 - B. Enrollees must be allowed to refill a transition supply of a non-formulary Part D drug if the prescription is dispensed for less than the written amount due to QLs for safety purposes or drug utilization edits that are based on approved product labeling.
 - C. All non-formulary, PA, ST, or QL edits are to be resolved at point-of-service adjudication. No "hard edits" are utilized in order to manage transition supplies. Since UM edits (except Part B vs. Part D or Part D vs. Part D-excluded prior authorizations, edits to reject non-part D drugs, QLs for safety reasons, and early refill edits) are overridden to allow a transition fill during the first 108 days of enrollment, there is no need for retail, home infusion, safety-net, or ITU pharmacists to enter an override. These claims pay without any additional input from the submitting pharmacist, and the enrollee, therefore, never leaves the pharmacy without a transition supply.

5.11 MESSAGING

During the transition period, the Company's claims system allows a transitional fill for all products identified as transition eligible. The Company's coding and claims processing system allows temporary supplies of non-formulary Part D drugs (including Part D drugs that are on the formulary but require PA, ST, QL-type PA under UM rules). The claims processing system has an automated configuration that determines whether or not the criteria for a transition supply is met. Claims are processed at POS and do not require additional action from the pharmacist unless an allowable edit is in place. This accommodates the immediate needs of an enrollee, as well as allowing the Company and/or enrollee sufficient time to work with 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.

5.11.1 If a transition fill is effectuated, the dispensing pharmacy receives:

- A. A free text message in the pharmacy response identifying this as a transition fill and other information related to authorization processing as needed.
- B. NCPDP-approved message codes in the pharmacy response. The pharmacy only receives NCPDP reject codes relative to transition and is dependent on pharmacy's software to apply appropriate message.
- C. When a transition supply claim is paid through the system, pharmacies are notified via an electronic message informing them that fill was part of a transition supply. If the claim encounters a valid transitional reject, a message is returned to the pharmacy to indicate reason for rejection.

5.11.2 Once the transition period has ended, the system rejects those claims for which products are non-formulary, need PA, or exceed plan limitations.

5.12 TRANSACTIONAL CODING IMPLEMENTATION

5.12.1 Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, the Company is to promptly implement either:

- A. Appropriate system changes to achieve goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim, or
- B. Alternative approaches that achieve goals intended in the messaging guidance

5.13 DETERMINING ONGOING THERAPY

The Company 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 POS.

5.13.1 For enrollees who remain in the same plan and are on a drug as a result of an exception that was granted in the prior year:

- A. Plans have the option of "honoring" exceptions that were granted in the prior year beyond the end of the plan year (i.e., plan may choose to honor an exception for as long as the enrollee remains in the plan).
- B. If a plan is NOT going to honor an exception beyond the end of the plan year, it must either:
 - 1) Offer to process a prospective exception request for the current plan year, or
 - 2) Provide enrollee with a temporary supply of requested prescription drug at beginning of current plan year and provide enrollee with notice that they must either switch to a therapeutically appropriate drug on the plan's formulary or get an exception to continue taking the requested drug

5.13.2 Protected Class Drugs

- A. Enrollees who receive a transition supply of a PA or ST (formulary) protected class drug may continue taking that medication throughout the benefit year.
- B. They are not to be considered “new starts” and do not need to go through coverage determination and exception process in order to continue on medication.
- C. These members are not to be sent a transition letter since they will continue on their therapy without interruption.

5.14 TRANSITION NOTIFICATION

- 5.14.1 Transition supplies are identified by the adjudication system based on specific indicators on the claim.
- 5.14.2 For transition claims, “Formulary Change across Contract Year” and “Level-of-Care Emergency Fill” transition claims, each claim is stamped with a transition claim indicator.
- 5.14.3 These indicators are used to define the type of transition and the reason for the transition, as defined in the CMS transition letter template (i.e., non-formulary, PA, ST, etc.).
- 5.14.4 If a temporary fill is provided for a Part D drug under applicable transition process, an appropriate written notice regarding the transition process is mailed within three (3) business days of the temporary fill submitted by provider.
- 5.14.5 The Company sends written notice to both the enrollee and the prescriber via U.S. first- class mail within three (3) business days of adjudication of a temporary fill. The notice must include:
 - A. Explanation of temporary nature of transition supply an enrollee has received
 - B. Instructions for working with plan sponsor and enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary
 - C. Explanation of enrollee's right to request a formulary exception
 - D. Description of procedures for requesting a formulary exception
- 5.14.6 For LTC residents dispensed multiple supplies of a Part D drug in increments of 14 days or less, consistent with the requirements of 42 CFR §423.154(a)(1)(i), written notice is to be provided within three (3) business days after adjudication of first temporary fill.
- 5.14.7 The CMS- approved template provided by the client is utilized for transition notification.

5.15 AVAILABILITY OF FORMS FOR PAs AND FORMULARY EXCEPTIONS

Upon request, the Company makes available PA or exception request forms to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on plan sponsor's websites. The forms, however, are not required; they are provided for convenience.

The Company provides clients with the Transition Process policy to ensure enrollees are provided access via plan sponsor's website which can be accessed directly or via a link from Medicare Plan Finder and in their pre- and post-enrollment marketing materials.

5.16 EXTENSION OF TRANSITION ON CASE-BY-CASE BASIS

- 5.16.1 The Company makes 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).

5.16.2 Extensions need to be initiated by the beneficiary, beneficiary's authorized representative, prescriber, or pharmacy. Requests may be made in writing, telephonically, or by email or fax.

5.17 TRANSITION ACROSS CONTRACT YEARS

5.17.1 For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Company will effectuate a meaningful transition by either: (1) providing a transition process at the start of the new contract year (See Option 1 below); or (2) effectuating a transition prior to the start of the new contract year (See Option 2 below). The Company extends its Transition Process policy across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply. Plan sponsors have two options to provide a meaningful transition to existing enrollees:

- A. Option 1: Part D sponsor has implemented a transition process for current enrollees consistent with the transition process required for new enrollees. In order to prevent coverage gaps, sponsors choosing this option provide a temporary supply of requested prescription drug (where not medically contraindicated) and provide enrollees with notice that they must either switch to a drug on the sponsor's formulary or get an exception to continue taking the requested drug.
- B. Option 2: Part D sponsor effectuates a transition for current enrollees prior to January 1 and works aggressively to both prospectively transition current enrollees to a therapeutically appropriate formulary alternate and/or complete requests for formulary and tiering exceptions to the new formulary prior to January 1. If an exception is granted, the sponsor authorizes payment prior to January 1 of the next contract year. If enrollees have not successfully transitioned to a formulary alternative, or had an exception request processed prior to January 1, the sponsor provides a transition supply beginning January 1 until they have effectuated a meaningful transition.

5.17.2 Combination Approach

- A. There is a combination of both CMS options for effectuating transitions for enrollees whose drugs are no longer on the formulary, or have had a PA, ST, or QL added effective January 1 of the next contract year.
- B. There is a transition process for current enrollees consistent with transition process required for new enrollees; AND notification and encouragement for current enrollees to transition to a therapeutically appropriate formulary alternate and/or complete requests for formulary and tiering exceptions to the new formulary prior to the start of the new contract year (per PDBM, Chapter 6, Section 30.4.5).
- C. To ease volume of member calls and authorization requests as of January 1, enrollees and/or their providers are encouraged to proactively seek non-formulary exceptions (and other exceptions for drugs that have had UM added) prior to the beginning of the next contract year.
- D. The Company supports enrollee notification of formulary changes across contract years using various methods, and the client chooses one or more of these methods to provide ample opportunity for members to proactively seek a non-formulary exception:
 - 1) Annual ANOC (not sufficient notice by itself)
 - 2) EOBs in November and/or December
 - 3) Online notification tables (not sufficient notice by itself)
 - 4) Direct enrollee mailings
 - 5) Client newsletters (not sufficient notice by itself)
 - 6) Email blasts

5.17.3 When such exceptions have been approved, the enrollee is able to continue on medication

through the end of that contract year (ensuring payment is authorized prior to January 1), and through the next contract year in accordance with the “Coverage Determinations” policy and based on the CMS-approved coverage duration defined in the PA criteria.

- 5.17.4 If the enrollee, an authorized representative, or prescribing physician has not requested an exception prior to the end of the contract year, the enrollee, their authorized representative, or the prescribing physician must still request a coverage determination exception review as expeditiously as possible.
- 5.17.5 If the enrollee has not successfully transitioned to a formulary alternative by January 1, the Company provides a transition supply beginning January 1, consistent with the process for new enrollee transitions, by programming the negative formulary changes across contract years (drugs that have UM added or have become non-formulary) to allow the additional transitional fill for current beneficiaries who utilized the drug during the past at least 120 days.

5.18 TRANSITION REPORTING AND DOCUMENTATION

- 5.18.1 The Company's manager of Medicare communication or their designee provides relevant client advisor personnel the following reports and information quarterly, or more frequently, as required by specific clients:
 - A. Transition fulfillment report outlining transitions granted and notices sent
 - B. Compliance reporting for information regarding timeliness of fills and transition notice fulfillment
- 5.18.2 The Company also provides the Part D sponsor with data including support of the Transition Monitoring Program Analysis activity.

P&T COMMITTEE / MEDICAL POLICY GROUP RESPONSIBILITIES

- 5.18.3 The Company ensures that the P&T Committee/Medical Policy Group review provides recommendations regarding procedures used for medical review of drugs requiring PA, ST, QL, or non-formulary drug requests.
- 5.18.4 P&T Committee/Medical Policy Group involvement ensures that transition decisions appropriately address situations involving:
 - A. Enrollees stabilized on drugs that are not on client's formulary and that are known to have risks associated with any changes in the prescribed regimen
 - B. Enrollees stabilized on drugs that are on the client's formulary but require PA, ST, or QL-type PA under its UM requirements and that are known to have risks associated with any changes in the prescribed regimen
- 5.18.5 The P&T Committee reviews this transition policy at least annually to ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs, either non-formulary drugs or formulary drugs, that require PA, ST, or QL, and which may have risks associated with a change in the prescribed regimen.

5.19 TRANSITION SUPPLY OPTIONS

- 5.19.1 Each plan sponsor may choose to provide the CMS minimum-required transition supply or can provide a greater amount than the required minimum. Each sponsor is to notify the Company of their transition policy each year to ensure accurate set-up in the claims adjudication system.

5.20 ATTESTATION CROSSWALK

5.20.1 The following grid provides a crosswalk of the attestations to the applicable portion of this policy and associated procedures to support the requirements.

Attestation #	Description	Policy Location
1	Optum Rx 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, and (5) enrollees residing in long-term care (LTC) facilities.	Section 2.1
2	Optum Rx will submit a copy of its transition policy to the plan sponsor.	Section 5.1.1
3	Optum Rx 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 quantity limit (QL) lower than the beneficiary's current dose, under a plan's utilization management rules. Optum Rx will ensure that its Transition 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.	Section 5.2.1 Transition Supply for Non-Formulary Drugs Section 5.2.2 Actions Taken if Medical Necessity Determination Fails Section 5.3 Transition Supply for Drugs with UM Controls
4	Optum Rx will have systems capabilities that allow for 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.	Section 5.2 Transition Supply for Non-Formulary Drugs
5	Optum Rx will ensure that in the retail setting, the Optum Rx Transition Policy provides a one-time, temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case Optum Rx will allow multiple fills to provide up to a total of a month's supply of medication) at any time during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.	Section 5.5.1 Retail Setting- up to a month's supply

Attestation #	Description	Policy Location
6	Optum Rx 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, a sponsor 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.	Section 5.6 Cost-Sharing on Temporary Fills
7	Optum Rx will ensure that in the long-term care setting: (1) the Optum Rx 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 Optum Rx 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.	Section 5.7 Transition for LTC Setting
8	Optum Rx will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or B versus Part D coverage, edits to prevent coverage of non-Part D drugs, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale.	Section 5.3.1. Transition Supply for Drugs with UM Controls Section 5.10 Quantity Limits, Refill- too-soon, and Safety Edits
9	Optum Rx will ensure that the Optum Rx 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.	Section 5.10 Quantity Limits, Refill- Too-Soon, and Safety Edits
10	Optum Rx 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.	Section 5.13 Determining Ongoing Therapy
11	Optum Rx will send written notice consistent with CMS transition requirements.	Section 5.14 Transition Notification

Attestation #	Description	Policy Location
12	Optum Rx will make available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including, mail, fax, email, and on plan websites.	Section 5.15 Availability of Forms for PAs and Formulary Exceptions
13	The Optum Rx Transition Policy will extend across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.	Section 5.17.1 Transition Across Contract Years
14	Optum Rx will coordinate with Plan Sponsors to make the Optum Rx Transition Policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor website and include in pre- and post-enrollment marketing materials as directed by CMS.	Section 5.15 Client Obligation - Sponsors to Make Transition Policy Available to Enrollees
15	Optum Rx 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).	Section 5.16.1 Extension of Transition on Case-by-Case Basis
16	For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, Optum Rx 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 period prior to the start of the new contract year.	Section 5.4 Transition for Newly Implemented UM Controls Section 5.17.1 Transition Across Contract Years

5.21 Client Obligation - SPONSORS TO MAKE TRANSITION POLICY AVAILABLE TO ENROLLEES

- 5.21.1 The Company provides a copy of this Transition Process policy to the plan sponsor on an annual basis.
- 5.21.2 This policy is reviewed and approved by the Company's P&T Committee.

- 5.21.3 The plan sponsor is then responsible for additional P&T reviews and submission to CMS or to provide CMS their own Transition Process policy for review and approval.
- 5.21.4 The plan sponsor is also responsible for making the Transition Process policy available to Medicare beneficiaries in post-enrollment marketing materials.
- 5.21.5 The Company monitors CMS guidance and makes updates or revisions to current policy as needed.

5.22 End of Procedure

6.0 RELATED CONTROLLED DOCUMENTS

- 6.1 Policies
 - 6.1.1 N/A
- 6.2 Procedures
 - 6.2.1 N/A
- 6.3 Work Instructions
 - 6.3.1 N/A
- 6.4 Other Documents
 - 6.4.1 JA-5487 Processing Controlled Documents

7.0 ATTACHMENTS

- 7.1 N/A

8.0 AUTHORITY/CITATIONS

- 8.1 N/A

9.0 CHANGE LOG

- 9.1 Section will be completed and filled out by Submitter and Document Control.

Version	Date	Change to Document	Contributor
1	05/14/2018	Initial Document	Catherine Wesselink
-	05/22/2018	Updated template, no content changes	A Gonzalez
2	05/14/2019	Minor grammatical updates to Attestations 3 and 5. Removal of Attestation 17 per CMS.	Catherine Wesselink
3	07/22/2019	Updated section 5.2.2.B, see Attestation 3	Catherine Wesselink
4	03/25/2020	Updated non-formulary drug definition in section 4.23 and referenced compound claims in section 5.2.1	Catherine Wesselink

5	10/27/2020	Removed section 5.18.4 which provides a one-time override for temporary month's supply on the last day of a contract year when there is a pending decision on a coverage determination or exception. This is no longer required due to system enhancements. Section 5.18 re-numbered.	Catherine Wesselink
6	05/19/2021	Updated transition window to 108 days instead of 90 days.	TyShawn Banks
7	05/13/2022	Updated dates to reflect current year. No content changes.	Cyndi Tinkle
8	05/19/2022	Updated reviewers to remove Jeffrey Murphy and add Anand Mehta. Minor clarifications to sections 4.23, 5.2, 5.3, 5.8, 5.10, 5.23.	Cyndi Tinkle, Iny Marks
9	10/12/2022	Updated sections: 2.1, 4.24, 5.16, 5.2, 5.2.2, 5.3.2, 5.5.2, 5.6, 5.8.4, 5.9.1, 5.9.2, 5.9.3, 5.9.6, 5.10.6, 5.13.2, 5.14.7, 5.23	Sheri Oswald, Beth Shocklee, Iny Marks, Janice Harter, Mark Noga, Alison Hirsch
10	03/14/2023	Updated dates to reflect current year and Section 5.20 to update "The Company" to "Optum Rx". Minor updates to Crosswalk Attestation # 2, 5	Cyndi Tinkle Beth Shocklee
11		Update 5.6 D, Annual Review Date	Steve Violette