| Policy Title: | 2020 Transition Policy | | |
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**Purpose:**
To provide members with a temporary supply of medications in certain circumstances that would not otherwise be covered. The intent of this supply is to allow for continuity of care so that members can work with their prescribers to switch to a covered formulary alternative or initiate a coverage determination for the prescribed drug.

**Scope:**
MMP

**POLICY**
The Delegated PBM transition policies are as follows:
1. Delegated PBM implements and maintains an appropriate transition process, as approved by CMS and each specific state administering the MMP Demonstration to ensure consistency with CMS and state rules and guidance. The Delegated PBM process allows a meaningful transition for the following groups of Beneficiaries whose current drug therapy may not be covered by the Sponsor: (a.) new Beneficiaries enrolled into the prescription plan following the annual coordinated election period; (b.) newly eligible MMP Beneficiaries from other coverage; (c.) the transition of Beneficiaries who switch from one plan to another after the start of a Contract Year; (d.) current Beneficiaries affected by negative formulary changes across Contract Years; (e.) Beneficiaries residing in long-term care (LTC) facilities, including Beneficiaries being admitted to or discharged from an LTC facility.
2.  The Sponsor is responsible for submitting a copy of its transition policy process to CMS to comply with CMS and/or state requests.
3. The transition policy will apply to Non-formulary MMP Drugs. This includes Non-formulary Part D Drugs, meaning: (a.) Part D drugs that are not on a Sponsor's formulary; (b.) Part D drugs previously approved for coverage under an exception once the exception expires; and (c.) Part D drugs that are on a Sponsor's formulary but require Prior Authorization or step therapy or when approved quantity limit edits, are lower than the Beneficiary's current prescribed dose, under a Sponsor's utilization management rules. Non- Formulary MMP Drugs also include Non-formulary Medicaid benefit (state-defined) Drugs meaning both: (a) Medicaid drugs that are not on a Sponsor's Additional Demonstration Drugs (ADD) file but are included on the Sponsor's Transition of Care list; and (b) drugs on the ADD file but require Prior Authorization, step therapy, or quantity limit edits under a Sponsor's utilization management edits. Each Sponsor provides Delegated PBM a list which includes drugs that

can be authorized for a Medicaid Transition of Care fill. The MMP transition process allows for medical review of Non-formulary MMP Drug requests, and when appropriate, a process for switching new MMP plan Beneficiaries to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination. The Delegated PBM will handle Biosimilars as non-interchangeable brand/generic products for its programs and processes involving transition fill and will apply the appropriate cost share according to CMS guidance. For Sponsors delegating formulary management to the Delegated PBM, Delegated PBM's **P&T committee should meet on a regular basis, but no less than quarterly and review** procedures for coverage determination and exceptions, and, if appropriate, a process for switching new Beneficiaries to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination**.** For 2020, Sponsor is delegating formulary management to Delegated PBM.

4. The Delegated PBM will have systems capabilities that allow Delegated PBM to provide a temporary supply of a Non-formulary MMP drug in order to accommodate the immediate needs of a Beneficiary, as well as to allow the plan and/or the Beneficiary 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. The Delegated PBM Transition Fill (TF) processing and coding applies point-of-sale (POS) messaging to pharmacies.

5. The Delegated PBM MMP transition process for Non-formulary Part D drugs will apply in the non-LTC setting such that the transition policy provides a one-time temporary fill of at least the applicable month's supply of medication (unless the Beneficiary presents a prescription written for less than a month's supply in which case the Sponsor must allow multiple fills to provide up to a total of the applicable month's supply of medication)anytime during the first 90 days of a Beneficiary's enrollment in a plan or greater as specified by MMP, beginning on the Beneficiary's effective date of coverage. The Delegated PBM MMP transition process for Non-formulary Medicaid benefit drugs will apply according to the Sponsor's MMP contract and plan design. These quantity and time plan limits may be greater based on the Sponsor's benefit design and will be limited by the amount prescribed. Refer to Exhibit A for additional plan design details. For 2020, the Sponsor's plan set up allows for a 90 day supply within the 90 day TF Window.

6. The Delegated PBM will apply the Sponsor's cost-sharing tier for a temporary supply of drugs provided under its transition process such that it will not exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible Beneficiaries. For non-LIS Beneficiaries:
   a. Non-formulary Part D drugs transition supply will receive the same cost sharing that would apply for non-formulary drugs approved through a formulary exception.
   b. Formulary transition supply will receive the same cost sharing for a formulary drug subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.

7. The Delegated PBM Part D transition process in the LTC setting will include the following attributes: (a.) the transition policy will provide for a one time temporary fill of at least an applicable month's supply (unless the Beneficiary presents with a prescription written for less) consistent with the applicable dispensing increment in the LTC setting, with refills provided if needed during the first 90 days of a Beneficiary's enrollment in a plan or greater as specified by MMP, beginning on the Beneficiary's effective date of coverage; (b.) after the

transition period has expired or the days supply is exhausted, the transition policy will provide for at least a 31-day emergency supply of non-formulary Part D drugs (unless the Beneficiary presents with a prescription written for less than the 31 days supply) while an exception or Prior Authorization determination is pending; and (c.) for Beneficiaries being admitted to or discharged from a LTC facility, early refill edits will not be used to limit appropriate and necessary access to their MMP benefit, and such Beneficiaries will be allowed to access a refill upon admission or discharge. Delegated PBM Medicaid Transition of Care will be identified through the MMP contract and the plan design. For 2020, the Sponsor's plan set up allows a month's supply of 31 within the 90 day TF Window for LTC and New Patient/Level of Care Change. LTC Emergency Supply allows a 31 days supply; LTC Emergency Supply is allowed per rolling 30 days.

8. The Delegated PBM will only apply the following utilization management edits during transition at POS: 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 will be coded to be resolved at POS.

9. Delegated PBM transition process will allow 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.

10. Delegated PBM will apply its transition processes to a brand-new prescription for a Non-formulary MMP Drug if it cannot make the distinction between a brand-new prescription for a Non-formulary MMP Drug and an ongoing prescription for a Non-formulary MMP Drug at POS.

11. For Sponsors using the Delegated PBM to fulfill their Part D transition notices, the Delegated PBM will send written notice via U.S first class mail to the Beneficiary within three business days of the adjudication of a temporary transition fill. The notice will include (a.) an explanation of the temporary nature of the transition supply a Beneficiary has received; (b.) instructions for working with the Sponsor and the Beneficiary's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Sponsor's formulary; (c.) an explanation of the Beneficiary's right to request a formulary exception; and (d.) a description of the procedures for requesting a formulary exception. For LTC residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less, the written notice will be provided within 3 business days after adjudication of the first temporary fill. For Sponsors using Delegated PBM to fulfill their Medicaid TOC notices, Delegated PBM will send the TOC notice within the Sponsor's MMP contract requirements. Delegated PBM will use the transition notice(s) provided by the Sponsor. Sponsor will seek to obtain CMS approval for the notice submitted by using the CMS model Transition Notice via the file-and-use process, if required or submitting a non-model Transition Notice to CMS for marketing review subject to a 45-day review. Delegated PBM will use reasonable efforts to provide notice of transition to prescribers to facilitate transitioning of Beneficiaries. For Sponsors not using Delegated PBM to fulfill transition notices, a daily extract file is provided to the Sponsor containing Part D TF paid transactions requiring a transition notice and a separate file is provided containing all of the Medicaid TOC transactions. For 2020, Sponsor is using Delegated PBM to fulfill transition notices.

12. For Sponsors using Delegated PBM for coverage determinations, Delegated PBM will make available Prior Authorization or exception request forms upon request to both Beneficiaries and prescribing physicians via mail, fax, email, and with the Sponsor via their plan web sites.

For Sponsors not using Delegated PBM for coverage determinations and exceptions, the Sponsor is responsible for providing these forms. For 2020, Sponsor is using Delegated PBM for coverage determination. OR For 2020, Sponsor is responsible for coverage determinations. (Also update Procedure and Impl Stmt 12 regarding this activity).

13. Delegated PBM will extend its MMP transition policy across Contract Years should a Beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.

14. Sponsor is responsible for making general transition process information available to Beneficiaries via the Medicare Prescription Drug Plan Finder link to Sponsor's web site as well as in Beneficiary formulary and pre- and post-enrollment materials.

15. The Delegated PBM will provide a process for Beneficiaries to receive necessary MMP drugs 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 transaction 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 2020, Sponsor will allow a 30 days supply for transition extension.

16. Delegated PBM will implement the transition process for renewing Beneficiaries whose drugs will be affected by negative formulary changes in the upcoming Contract Year. Delegated PBM will offer Sponsors transition processes for encouraging a transition prior to the beginning of the Contract Year. The Sponsor plan set up for Renewing Beneficiary history review is at a GPI 10 level with a look back of 180 days.

17. Delegated PBM will maintain the ability to support routine and CMS or State-required reporting, as well as the ability to respond to ad hoc requests for: (a.) denied claim reports and (b.) paid transition claim reports for new and renewing Beneficiaries. It will also maintain the ability to support test transition claim processing in response to ad hoc requests and regularly reviews and audits transition program data and system operations to monitor adherence with MMP transition requirements.

18. Members taking Non Formulary Test Strips will obtain a transition fill for 180 days from joining the plan.


**DEFINITIONS** (All defined words in this document are displayed with initial capitals, except for acronyms.)

1. **Additional Demonstration Drugs (ADD):** Drugs (prescription and over the counter) and durable medical equipment not covered by Medicare Part D and covered by Medicaid. Each state involved in a MMP Demonstration separately defines the drugs covered by its Medicaid benefit and the drugs included on its ADD file.

2. **Annual Notice of Change (ANOC)**: The CMS required document that must be sent to all current Beneficiaries annually in accordance with CMS directions, and that describes changes to existing benefits that are expected for upcoming new Contract Year.

3. **Applicable Month's Supply**: CMS required transition supply for Part D drugs, as a minimum (unless prescriptions are written for fewer days); the supply is determined as the number of days submitted on the applicable Plan Benefit Package (PBP) submitted to CMS for the relevant plan year. CMS approval determines the approved month's supply for

Beneficiaries in both the non-LTC and LTC settings. Multiple fills up to a total month's supply are allowed to accommodate fills for amounts less than prescribed.

4. **Beneficiary**: An individual enrolled in a Delegated PBM Sponsor'ss MMP, also known as an Enrollee or Member.

5. **Biosimilars:** A biological product submitted to the FDA for approval via the biological abbreviated pathway created by 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.

6. **Capitated Financial Alignment Initiative (or "Demonstration"):** A model where a State, CMS, and a health plan (Sponsor) enter into a Three-way Contract and the health plan receives payment to provide comprehensive care.

7. **CMS:** U.S. Centers for Medicare and Medicaid Services.

8. **Contract:** Also referred to as the Three-way Contract. This is the participation agreement that CMS and a State have with Sponsor specifying the terms and conditions pursuant to which Sponsor may participate in the Capitated Financial Alignment Initiative.

9. **Contract Year:** The period for which a particular plan benefit package applies. Also known as the "plan year." In the case of the transition period for current Beneficiaries across contract years in non-calendar plans, the term "contract year" refers to the calendar year for which the new formulary is effective.

10. **Delegated PBMDelegated PBM:** Sponsor's pharmacy benefit manager**.**

11. **DUR:** Drug Utilization Review that does not allow override of select DUR safety edits which are set up to reject at point of sale.

12. **Food and Drug Administration (FDA):** A government agency, under the U.S. Department of Health and Human Services.

13. **Generic Product Identifier (GPI):** A 14-character hierarchical classification system created by Medi-Span. It identifies drugs available with a prescription in the United States to a manufacturer and pill level.

14. **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 health care provider who prescribed the reference product.

15. **Long-term Care** (**LTC**)**:** Long-term care refers to facilities or institutions, such as nursing homes and skilled nursing facilities that provide healthcare to people who are unable to manage independently in the community. This care may represent custodial or chronic care management or short-term rehabilitative services.

16. **Low-income Cost-sharing Level III (LICS III):** Designation provided by CMS. The CMS LICS III eligibility designation plus the pharmacy submitted codes are evaluated for a claim to be eligible for LICS III benefits.

17. **Low Income Subsidy (LIS):** Subsidized premiums, deductibles, and copayments for which Eligible Beneficiaries may be qualified. Also referred to as Extra Help.

18. **Medicaid:** State programs of public assistance for eligible persons, whose income resources are insufficient to pay for health care under the Social Security Act.

19. **Medicare Part D (Part D):**  Medicare Prescription drug benefit under Part D of the Social Security Act.
20. **Medicare-Medicaid Plans (MMP):**  A product offering sponsored by both the Federal and State governments that combines the current Medicare and Medicaid programs into a single benefit offering for dually eligible individuals.
21. **MME:**  Morphine Milligram Equivalent
22. **Multi-Ingredient Compound (MIC):**  referring to the logic for the determination of reimbursement and coverage of a claim that consists of multiple ingredients which are manually assembled and dispensed by a pharmacy.
23. **National Council of Prescription Drug Programs (NCPDP):**  An American National Standards Institute (ANSI) accredited group that maintains a number of standard formats for use by the retail pharmacy industry, some of which have been adopted as Health Insurance Portability and Accountability Act (HIPAA) standards.
24. **National Drug Code (NDC):**  The National Drug Code is a unique, 3-segment numeric identifier assigned to each [medication](medication) listed under Section 510 of the US Federal [Food, Drug, and Cosmetic Act](Food,-Drug,-and-Cosmetic-Act).
25. Neighborhood INTEGRITY: the plan sponsor.
26. **Non-formulary Part D Drugs**:  This means: (a.) Part D drugs that are not on Sponsor's formulary; and (b.) Part D drugs previously approved for coverage under an exception once the exception expires and (c.) Part D drugs that are on Sponsor's formulary but require Prior Authorization, step therapy, or approved quantity limit edits, lower than the Beneficiary's current dose, under Sponsor's utilization management rules.
27. **Non-formulary Medicaid benefit Drugs:** This means both: (a) Medicaid drugs that are not on Sponsor's Additional Demonstration Drugs (ADD) file but are included on Sponsor's Transition of Care list; and (b) drugs on the ADD file but require Prior Authorization, step therapy, or quantity limit edits under Sponsor's utilization management edits. Each state defines its Medicaid benefit drugs and its ADD file.
28. **Non-formulary MMP Drugs:** This means both Non-formulary Part D Drugs and Non-formulary Medicaid benefit Drugs.
29. **Non-Long-Term Care:**  Describes Retail, Mail and Home Infusion facilities.
30. **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.
31. **PAMC:**  Prior Authorization/Medical Certification Code.  This is a field on the standardized pharmacy adjudication layout for entry of an authorization code provided by the processor.
32. **Patient Location Code (PLC):**  RxClaim adjudication legacy system value that crosswalks from the Pharmacy Service Type and Patient Residence Type Code.
33. **Patient Residence Type (PR):**  **P**harmacies collect and record the patient residence at point of sale on the claim.
34. **PCD:**  Protected Class Drug
35. **Pharmacy Service Type (PST):**  The type of service being performed by a pharmacy when different contractual terms exist between a payer and the pharmacy, or when benefits are based upon the type of service performed.

36. **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.
37. **Print Fulfillment:** Delegated PBM business unit(s) that are responsible for the print fulfillment of some Beneficiary notifications including transition fill notifications to Beneficiaries and prescribers.
38. **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 Beneficiary's insurance plan.
39. **RxClaim:** Delegated PBM **information technology system that serves to process and adjudicate Part D claims; otherwise known as the "system," "platform," or "system platform."**
40. **Sponsor:** A MMP Sponsor that contracts with Delegated PBM for pharmacy benefit management services including implementation of its transition process. Also known as the Plan, Plan Sponsor or Client. Sponsor is Neighborhood INTEGRITY.
41. **STCOB:** Single Transaction Coordination of Benefits
42. **Submission Clarification Code (SCC):** NCPDP data element indicating that the pharmacist is clarifying the claim submission.
43. **TF Window:** The Beneficiary TF Window or timeframe is the Sponsorspecified number of days (minimum of 90 days) during which Beneficiary transition benefits apply.
44. **Transition:  a process that provides a temporary supply of MMP drugs (includes both TF and TOC).**
45. **Transition Fill - Medicare (TF):  A temporary supply of a Part D covered drug per CMS Part D requirements paid under the benefit of the MMP product.  TF is part of a MMP's transition process (transition) for Beneficiaries.**
46. **Transition of Care – Medicaid (TOC):  A Medicaid plan process to provide a temporary supply of a drug paid under the Medicaid benefit of a MMP product.  TOC is part of a MMP's transition process (transition) for Beneficiaries.**


**PROCEDURES**
1. Sponsor's transition program is implemented by Delegated PBM according to the Sponsor's requested benefit design.
   a. Transition supplies are provided at POS to eligible Beneficiaries which are coded as the following:
      i. New Beneficiaries in the MMP following the annual coordinated election period
      ii. Newly eligible MMP Beneficiaries from other coverage
      iii. Beneficiaries who switch from another MMP plan after the start of a Contract Year
      iv. Current Beneficiaries affected by negative formulary changes
      v. Beneficiaries residing in LTC facilities
   b. Transition supply limits applicable to Non-formulary Part D drugs are defined as cumulative days supplies calculated on Generic Product Identifier (GPI) 14 and are not based on number of fills.  Transition supply limits applicable to Non-formulary Medicaid benefit Drugs are defined by each state as cumulative days supply calculated on GPI 14.
   c. Transition-eligible claims submitted for LICS III Beneficiaries are processed according to Beneficiary's LICS Level and pharmacy submitted codes to determine if the claim received will be processed as non-LTC, LICS III or LTC.

2. Delegated PBM will maintain a MMP transition process policy and procedure and review, and if needed, revise, the document at least annually and as needed when processing changes occur.

3. Non-formulary Drugs
   a. Procedures to apply the transition policy to Non-formulary MMP Drugs are to obtain the Sponsor's P&T Committee approved formulary and UM edits, and code these into the adjudication system to therefore identify TF eligible claims at POS so that they will be paid.
   b. Notwithstanding any references in this document to expiring formulary exceptions, since CMS has issued guidance stating that it does not expect Part D Sponsors to include expiring formulary exceptions in their transition policies, Delegated PBM will not apply its transition policy to expiring formulary exceptions unless and until CMS issues guidance requiring otherwise.
   c. Procedures for medical review and identifying Formulary Alternatives are as follows:
      i. If a Sponsor uses Delegated PBM for operational appeals support, the coverage determination and medical review processes use procedures that ensure Beneficiaries have access to processes for medical review of Non-formulary MMP Drug requests.
      ii. Information regarding therapeutically appropriate formulary alternatives is made available to Beneficiaries and prescribers failing an affirmative medical necessity determination.
      iii. Beneficiaries who contact Customer Care and Pharmacies that contact the Pharmacy Help Desk are provided with information regarding available formulary alternatives when requested and as appropriate for Beneficiaries' care.
      iv. For Sponsors delegating coverage determination and redetermination to Delegated PBM, included in the delegated responsibilities is the review of the procedures for coverage determinations and exceptions that in some cases may result in the need for a process for transitioning a Beneficiary to a therapeutically appropriate formulary alternative.

4. POS transition fill processing is available and there are procedures in place for transition extensions and overrides, if needed, through the Pharmacy Help Desk and Customer Care. Transition POS messaging to pharmacies applies as follows:
   a. The Delegated PBM adjudication system automatically processes and pays transition-eligible claims and transmits POS messaging that the claims are paid under transition rules.
   b. MMP transition messaging to pharmacies is consistent with current National Council of Prescription Drug Programs (NCPDP) Telecommunication claim standards (at the time of this publication, the current standard is D.0 and hereafter referred to as "Current NCPDP Telecommunication Claim Standards"). Pharmacies are not required to either submit, or resubmit, a Prior Authorization/Medical Certification Code (PAMC), or other transition-specific code for MMP transition-eligible claims to pay.
   c. Transition processing applies to both new and ongoing prescriptions at POS and through the Pharmacy Help Desk for Beneficiaries who are new to a plan.
   d. Communication and educational outreach to network pharmacies is ongoing throughout the year to provide information and instructions regarding transition policies and claim processing. At least annually, and more often as needed, transition pharmacy communications are distributed through the pharmacy network department.

5. Transition for New or Renewing Beneficiaries in the Non-LTC setting
   a. In a Non-LTC setting, Delegated PBM adjudication system automatically processes and pays transition-eligible claims for new Beneficiaries for up to at least a cumulative applicable month's supply with multiple fills up to at least a cumulative applicable month's supply allowed to accommodate fills for amounts less than prescribed for Non-formulary Part D drugs or according to the MMP contract and plan design for Non-formulary Medicaid benefit drugs. Refer to Exhibit A for additional plan design details.
   b. Pharmacies are not required to either submit, or resubmit a PAMC, or other transition-specific code for transition-eligible claims to adjudicate and pay.
   c. Transitions are available at POS through this functionality during the TF window.
   d. The new and renewing Beneficiaries in a Non-LTC setting may have greater quantity and time plan limits based on the benefit design and will be limited by the amount prescribed.
   e. Non-LTC Level of Care Change
      i. For non-LTC residents, a transition may be provided automatically at POS, if the adjudication process indicates a Level of Care change from LTC to non-LTC. Otherwise, the pharmacy will call the Delegated PBM Pharmacy Help Desk in order to obtain an override to submit a Level of Care transition request.
6. Delegated PBM will establish the cost-sharing per the Sponsor's plan design.
   a. Cost-sharing for drugs supplied as a transition is set by statute for low-income subsidy (LIS) Beneficiaries.
   b. For non-LIS Beneficiaries:
      i. Non-formulary Part D drugs transition supply will receive the same cost-share as would apply if a non-formulary exception was applied in accordance with §423.578(b).
      ii. Formulary transition supply will receive the same cost sharing that would apply for a formulary drug subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.
7. Long-term Care Processing
   For LTC transitions, the Delegated PBM adjudication system automatically processes and pays transition-eligible LTC claims and transmits POS messaging that these are paid under transition. Part D LTC Transition Fills are allowed a cumulative applicable month's supply, except for brand oral 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. Multiple fills to provide up to a total of the applicable month's supply of medication are allowed consistent with the applicable dispensing increment in the LTC setting. Medicaid LTC Transition of Care fills will occur in the same time period as non-LTC transitions; however, the cumulative days supply will be in accordance with the MMP contract and plan design. These quantity and time plan limits may be greater based on the benefit design. Pharmacies are not required to either submit, or resubmit a PAMC, or other transition-specific code for transition-eligible claims to adjudicate and pay.
   a. LTC Transition Fill Emergency Supplies (ES)
      i. To accommodate Part D emergency fills for LTC residents after either the new or renewing transition supply has been exhausted or the TF window expired, and while an exception or Prior Authorization is pending, an SCC is submitted by the pharmacy on POS claims. Emergency Supply transitions for Part D TF are allowed up to at

least a cumulative 31 days supply except for brand oral solids which are limited to 14 day fills with exceptions as required by CMS guidance, unless submitted with an SCC of 21-36. These drug claims would otherwise reject for being Non-formulary or formulary with Prior Authorization, step therapy, quantity limit, or age edits secondary to Beneficiaries having exhausted new or renewing transition supply and/or being outside the transition eligibility window. Medicaid TOC benefit requirements for LTC ES are based on the MMP contract and plan design.

    ii. Part D LTC ES is allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan for the cumulative days supply during a rolling month, limited to one ES per LTC stay.

    iii. These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed.

  b. LTC Level of Care Changes

    i. For Part D TF for LTC residents, an SCC is submitted by the pharmacy to allow transitions and to override transition fill eligible rejects and Refill Too Soon rejects for new admissions. Level of Care transitions for Part D TF are allowed up to at least an applicable month's supply except for brand oral solids which are limited to 14 day fills with exceptions as required by CMS guidance, unless submitted with an SCC 21-36. These drug claims would otherwise reject for being Non-formulary or formulary with utilization management edits. Level of Care Transition Fills are allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan for a cumulative days supply

    ii. Medicaid TOC benefit requirements for Level of Care Changes are based on the MMP contract and plan design.

    iii. For all Beneficiaries who experience a Level of Care Change, if a dose change results in an "early refill" or Refill Too Soon reject, the pharmacy may call the Pharmacy Help Desk to obtain an override.

    iv. The quantity plan limits may be greater based on benefit design and will be limited by the amount prescribed.

  c. LICS III Beneficiaries

    i. LICS III processing logic is allowed on a transition-eligible claim for a LICS III Beneficiary with appropriate pharmacy submitted codes.

    ii. Transition eligible LICS III claims are allowed the cumulative days supply allowance set for LICS III by the Sponsor.

8. Utilization Management Edits Not Transition Eligible and Step Therapy and Prior Authorization processing

  a. Delegated PBM codes the following utilization management edits on drugs such that transition overrides are not applied:

    i. Drugs requiring Part A or B vs. Part D coverage determination as identified on the Delegated PBM drug database.

    ii. Drugs excluded from the MMP benefit as identified on the Delegated PBM drug database.

    iii. Edits to support the determination of Part D Drug Status.

    iv. DUR safety edits such as therapeutic duplication, cumulative acetaminophen, morphine milligram equivalent (MME), drug interaction, age alerts are set up to reject.

Step therapy, Prior Authorization and non-safety quantity limit edits are resolved at POS.

9. Cumulative Days Supply
   a. Transition refills for supplies dispensed at less than amount written, or less than the days supply available under transition rules are allowed multiple fills up to at least an applicable month's supply. Medicaid Transition of Care for new and renewing LTC Beneficiaries is based on the MMP contract and plan design.
   b. For DUR edits that are based on an FDA maximum recommended daily dose, Transition Fill claims which are dispensed at less than the written amount due to this edit are allowed refills during the TF Window.
   c. Delegated PBM transition cumulative supply accumulates at a GPI 14 level by Beneficiary and across Sponsor (or plan codes). LTC Emergency Supply and LTC Level of Care Change/New Patient benefits accumulate separately.
   d. These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed.

10. The Delegated PBM transition process is coded such that if the distinction cannot be made between a brand-new prescription for a MMP Non-formulary Drug and an ongoing prescription for a MMP Non-formulary Drug at the POS, the Delegated PBM transition process will be applied to the prescription as if it is ongoing drug therapy. This is referred to as the New Beneficiary process.

11. Transition Notices
    a. For Sponsors using Delegated PBM to fulfill Part D transition notices, a written transition notice is mailed via US First Class mail to the Beneficiary within three (3) business days after adjudication of a temporary fill. For Sponsors using Delegated PBM to fulfill their Medicaid TOC notices, Delegated PBM will mail the TOC notice within the MMP contract requirements.
    b. For LTC Part D Transition Fills for brand oral solids limited to a 14 days supply, a transition notice will be sent only after the *first* temporary fill.
    c. The transition notice
       i. Part D transition notice provides:
          1. an explanation of the temporary nature of the transition supply provided to the Beneficiary
          2. instructions for working with Delegated PBM and prescriber to satisfy utilization management requirements or to identify therapeutically equivalent and appropriate formulary alternatives
          3. an explanation of the Beneficiary's right to request a formulary exception
          4. a description of the procedures for requesting a formulary exception
       ii. Medicaid Transition of Care notice
          1. Delegated PBM will use the transition notice(s) provided by the Sponsor within system capabilities.
    d. Delegated PBM supports the use of the current CMS "Model Part D Transition Notice" for notification to Beneficiaries of the reasons for their Non-formulary Part D transition fills and recommendations for actions. Notwithstanding any reference in this policy to submitting a transition notice that uses the CMS model notice via the file and use system, since CMS has stated that this is not required, the model notice will not be submitted via the file and use process unless and until CMS requires this.

e. For Sponsors using Delegated PBM to fulfill transition notices, transition notices to prescribers are provided when a Beneficiary's transition notice is produced. The content of this notice is based on the content of the Beneficiary's transition fill notice, or CMS model notice if provided. Reasonable efforts are made to deliver the notice to the prescriber.

12. Availability of Prior Authorization and Exception Request Forms
    a. For Sponsors using Delegated PBM Prior Authorization and exception processing services, Prior Authorization and exception request forms are available upon request by Beneficiary or prescriber via a variety of means including by e-mail, mail, fax, and via forms posted on Delegated PBM websites.
    b. For Sponsors not using Delegated PBM for coverage determinations and exceptions, the Sponsor is responsible for providing these forms.

13. The Delegated PBM transition process for new Beneficiaries is coded to apply across Contract Years for Beneficiaries with an effective enrollment date at the end of the plan year and who need access to a transition supply for a negative formulary change. These Beneficiaries are eligible for a TF for a negative formulary change from the date they enroll in the current Contract year through the TF window, which starts on January 1 of the next plan year.

14. [Intentionally left blank to maintain consistent numbering between sections.]

15. Transition Extensions
    For Sponsors using Delegated PBM Customer Care, on a case-by-case basis, Delegated PBM Customer Care will provide an extension of the transition period to accommodate Beneficiaries who continue to await resolution of a pending Prior Authorization or exception request. The extensions are available through the Pharmacy Help Desk or Customer Care and per Sponsor's plan design.

16. Consistent with the transition fill process provided to new Beneficiaries, Delegated PBM provides transition(s), to renewing Beneficiaries during the TF Window of the Contract Year for Part D TF, or as defined by the MMP contract and plan design for Medicaid TOC, with a history of utilization of impacted drugs when those Beneficiaries have not been transitioned to a therapeutically equivalent formulary drug; or for whom formulary exceptions/Prior Authorizations are not processed prior to the new Contract Year who have been impacted by a negative formulary change. This applies at POS to all renewing Beneficiaries including those residing in LTC facilities.
    a. Renewing Beneficiary LTC transitions are available to all Beneficiaries in LTC settings during the TF Window for Part D TF, or as defined by the MMP contract and plan design for Beneficiaries with TOC who are impacted by a negative formulary change.
    b. For these Beneficiaries, the Delegated PBM adjudication system automatically processes and pays transition-eligible claims and transmits POS messaging that these are paid under transition rules.
    c. Additional transition supplies are available on a case-by-case basis through the Pharmacy Help Desk to ensure adequate transition. Pharmacies are not required to either submit, or resubmit a Prior Authorization/Medical Certification Code (PAMC), or other transition-specific code for transition-eligible claims to adjudicate and pay.
    d. Quantity and time limits may be greater based on plan benefit design and will be limited by the amount prescribed.

17. Transition Program Monitoring & Reporting

a. Transition processes are monitored both across and within each program area that has responsibility for transition processes. Transition program monitoring is both quantitative and qualitative.
b. Transition claim adjudication data are used to produce standard paid transition claim and rejected claim reports for quantitative program monitoring. Program performance monitoring includes reporting and monitoring of all transition types: new and renewing Beneficiary; and Level of Care Change and LTC Emergency Supply.
c. Support for and Response to Audit and Other Data Requests
   i. Audit requests for transition data from CMS, states, 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.
   ii. Non-urgent requests for transition data are responded to within ten business days. Other response times are available on case-by-case, as needed, basis.


**IMPLEMENTATION STATEMENT**
The following is a summary statement for how eligible claims process under transition adjudication system rules upon point of sale (POS) and manual submission to allow the override of system edits that would otherwise result in rejected claims. The objective of these transition adjudication system rules is to ensure pharmacies are able to resolve and override transition-eligible edits at POS toward the goal of ensuring Beneficiary access to medications per CMS and state requirements and guidance as part of the Capitated Financial Alignment Initiative.

1. The Adjudication System ensures that:
   a. Transition-eligible claims for new and ongoing prescriptions automatically adjudicate upon submission at POS for:
      i. New Beneficiaries in the MMP plan following the annual coordinated election period
      ii. Newly eligible MMP Beneficiaries from other coverage
      iii. Beneficiaries who switch from another MMP plan after the start of a Contract Year
      iv. Current Beneficiaries affected by negative formulary changes
      v. Beneficiaries residing in LTC facilities
   b. Transition processing is also available via manual overrides through the Pharmacy Help Desk.
   c. TF Window and eligibility check is applied to the claim
      The Beneficiary's MMP eligibility start date is provided by the Sponsor and based on plan design. Transition logic is not invoked if a claim exceeds either the TF Window or cumulative days supply based on Beneficiary's eligibility.
   d. Transition processing allows for transition supplies of different drug strengths
      Transition benefits (including Cumulative Days Supply) are set up based on Drug Generic Product Identifier (GPI) 14 to allow transition processing of different strengths of a drug under transition system rules. This ensures that a Beneficiary taking a drug with one strength is able to receive a transition for same drug/different strength if they present with a new prescription within transition-eligible time period.
      i. For Beneficiaries who are new to the MMP plan or renewing Beneficiaries within the TF Window of the Contract Year or as specified by the MMP contract and plan design; and for LTC level of care change and emergency supplies, transition for

dosage escalation is allowed, as appropriate, by manual override via the Delegated PBM Pharmacy Help Desk.

e. Part D Drugs only allowed for Part D TF

Non-Part D drugs are excluded from Part D transition processing. Non-Part D drugs are identified with an "N" in the "Med D" field on the Delegated PBM drug database. This enables the system transition logic to exclude non-Part D drugs from transition processing when claims for these drugs are submitted by pharmacies. Drugs that are covered under the Part D benefit and, therefore potentially eligible for Part D TF, are identified with a "Y" on the Med D field on the Delegated PBM drug database.

f. Non- Part D drugs and non-ADD file drugs only allowed for Medicaid TOC

Non- Part D drugs are identified with an "N" in the Med D field on the Delegated PBM drug database. Sponsors provide Delegated PBM a list which includes drugs that can be authorized for a Transition of Care (TOC) fill. This Sponsor-specific TOC eligible drug list will be coded at GPI level which enables the system transition logic to process Medicaid TOC claims according to plan design.

g. Multi-Ingredient Compounds processed for Part D TF

TF processing for Multi-Ingredient Compound (MIC) drugs is based on the formulary status of the claim. Depending on the MIC benefit design setup selected, the formulary status of the MIC claim can be based on the formulary status of the most expensive ingredient submitted or the formulary status of the entire claim (if all MICs are considered formulary, or all Non-formulary, or only topical MICs are considered Non-formulary and non-topical MICs are based on most expensive ingredient submitted). Non-formulary drugs will process under MIC TF rules. For MICs that are Non-formulary Drugs and generally covered only pursuant to an approved exception request, MIC drugs processed for TF are assigned the cost share applicable to the exception tier (i.e. the cost sharing applicable to Non-formulary Drugs approved pursuant to an exception request.) MIC transition supply for formulary drugs with a UM edit will receive the same cost share as would apply if the UM criteria is met.

Step 1: MIC adjudication determines the type of compound; determines if the MIC is a Part A or B or Part D drug. If the MIC is determined to be Part D eligible drug (no Part A or B ingredients and at least one Part D ingredient), then proceed to Step 2.

Step 2: Adjudication determines the formulary status of the Part D MIC claim based on benefit design; benefit setup determines if it is either formulary or Non-formulary.
   i. If the plan has designated all compounds or only topical compounds as Non-formulary, then the entire claim is considered Non-formulary and TF will apply.
   ii. If the plan bases the formulary status on the most expensive Part D ingredient:
      a. If the most expensive ingredient is a formulary drug, then all Part D ingredients in the MIC pay at contracted rates.
      b. If the most expensive ingredient is Non-formulary and is eligible for TF, then all Part D ingredients in the MIC pay as a TF. The TF letter refers to this prescription as a "compound" prescription.
      c. If the most expensive ingredient is not eligible for TF, the entire MIC will reject / not pay as TF.

For 2020, Sponsor will process MIC claims based on most expensive ingredient. The following edits will [not] be bypassed for MIC claims: QvT, daily dose and age.

    h.  Multi-Ingredient Compounds processed for Medicaid TOC
The standard Medicaid TOC set up (55556666777) has built-in logic that does not allow for MIC (with only Medicaid products) to pay under TOC.

2. This policy and procedure is updated at least annually in advance of the CMS Transition attestation window with the process changes expected for the following year. The policy is also updated as needed for additional changes.

3. Claims for MMP Non-formulary Drugs are eligible for "transition fill" and "transition of care" processing for valid adjudication under the Delegated PBM transition process.

    a.  Generic drug immediate substitution:  In the event of the launch of a new generic drug, the Sponsor or Delegated PBM on behalf of delegated template formulary Sponsor, will evaluate if the generic drug will be immediately added to the formulary and the brand drug changed to a Non-formulary status that is not TF eligible.

    b.  Beneficiaries with a current claim for a Part D drug that requires a quantity limit lower than the quantity limit on the beneficiary's history dose will be eligible for TF processing.

4. Systems capabilities exist to provide transition supplies at POS.  Pharmacies are not required to either submit, or resubmit a PAMC or other transition-specific codes for a transition-eligible claim to adjudicate.

    a.  POS Pharmacy Provider Notification

        i.  Pharmacies are notified at POS that claims have paid under transition rules, which is intended to assist pharmacies with discussing next steps with Beneficiaries.

        ii.  Transition processing information and communications are sent to all network pharmacies.  The transition processing information and communications include, though are not necessarily limited to the:  Pharmacy Provider Manual and all related updates; and the Medicare Part D Information/Reminders documents that are sent annually to network pharmacies prior to the beginning of each new Contract Year.

        iii.  Delegated PBM Pharmacy Help Desk (PHD):  Pharmacies contacting the PHD are verbally informed of a Beneficiary's transition availability, process, and rights for requesting Prior Authorization and/or exception, and how to submit an automated transition request.

        iv.  Auto-pay of transition-Eligible Claims
When submitted claims are eligible for payment under MMP Transition Fill rules, RxClaim adjudication system logic applies the TF PAMC  to the claim, tags the claim as a paid TF, and returns messaging on paid TF claims.  Pharmacies are not required to either submit, or resubmit a PAMC or other TF-specific codes for a TF-eligible claim to adjudicate.

    b.  For Sponsors using Delegated PBM to enter overrides, there are conditions under which it may be necessary for the Delegated PBM Pharmacy Help Desk or Customer Care to enter a manual transition override.  These situations include, but are not necessarily limited to:

        i.  Non-LTC Beneficiary moves from one treatment setting to another, if not identified automatically through the adjudication process

        ii.  Beneficiary has requested an exception and the decision is pending at the time the transition period expires, or the transition cumulative days supply exhausted

iii. Transition for dosage increase is needed
c. When manually entered with the transition PAMC, these transition overrides are adjudicated and tagged via the same processes as automated POS transition(s). The same messaging is returned to pharmacies on manual transition overrides as returned on automated paid transition claims. Transition letters are produced and sent to Beneficiary for manual transition overrides same as POS overrides.
5. Transition Supply & Time Period Parameters (and LTC Days Supply for Statement 7)
   a.

| Description | Transition Days Supply |
|---|---|
| New & Renewing Beneficiaries | |
| | • These quantity and time plan limits may be greater based on the benefit design and will be limited by the amount prescribed<br><br>• Part D TF<br>  o Non-LTC: cumulative applicable month's supply during the TF Window. Multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed. Refer to Exhibit A for additional plan design details.<br><br>  o LICS III: LICS III cumulative days supply as defined by the plan. Either non-LTC, LICS III, or LTC parameters are applied according to the LICS level, and pharmacy submitted codes.<br><br>  o LTC: cumulative applicable month's supply during the TF Window, brand oral solids are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36; multiple fills for a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed/ during the TF Window.<br><br>• State-specific Medicaid TOC requirements are shown in Exhibit A |
| Non-LTC Resident Level of Care Change | |
| • Beneficiary released from LTC facility within past 30 days | • These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed<br><br>• Part D TF |

| | |
|---|---|
| | <ul><li>Non-LTC: cumulative applicable month's supply; multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed.</li><li>LICS III: LICS III cumulative days supply as defined by the plan. Either non-LTC, LICS III, or LTC parameters are applied according to the LICS level and pharmacy submitted codes.</li><li>TF available at POS if identified through adjudication, otherwise through manual override via Pharmacy Help Desk on case-by-case basis.</li></ul><ul><li>Medicaid TOC requirements are shown in Exhibit A</li></ul> |
| **New and Renewing TF Extension** | |
| <ul><li>New or Existing Beneficiaries</li><li>Outside standard transition days supply or time period parameters</li><li>Transition parameters have been reached and Beneficiary is still pending exception/coverage determination decision</li></ul> | <ul><li>These plan limits will be limited by the amount prescribed</li><li>Part D TF</li></ul><ul><li>Non-LTC: Per Sponsor's plan design, via manual override, additional as needed as long as exception or coverage determination decision is pending.</li><li>LICS III: LICS III cumulative days supply as defined by the plan. Either non-LTC, LICS III or LTC parameters are applied according to the LICS level and pharmacy submitted codes.</li><li>LTC: per Sponsor's plan design, via manual override, additional as needed as long as exception or coverage determination decision pending</li></ul><ul><li>State-specific Medicaid TOC requirements are shown in Exhibit A</li></ul> |

b. LICS III Beneficiary benefit conversion
   A LICS III beneficiary is identified by the pharmacy submitted codes along with eligibility LICS Level of III.
c. Non-LTC Resident Level of Care Change

i. For non-LTC residents, a transition may be provided automatically at POS, if the adjudication process indicates a Level of Care change from LTC to non-LTC and the claim is rejecting for Refill Too Soon (R79) or DUR (R88). Otherwise, the pharmacy will call the Delegated PBM Pharmacy Help Desk in order to obtain an override to submit a Level of Care transition request.

ii. A Level of Care change from LTC to non-LTC is indicated in the adjudication process if the submitted drug matches a claim in the most recent 120 days of history on GPI 14 with a Patient Location Code indicating LTC. For Part D TF, the non-LTC residents are allowed cumulative applicable month's supply (or greater based on benefit design); multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed. Cumulative Days Supply for Medicaid TOC is defined by the MMP contract and plan design.

6. The adjudication system ensures that cost-sharing applied to the transition process for low-income subsidy (LIS) Beneficiaries never exceeds statutory maximum co-pay amounts. For non-LIS Beneficiaries, non-formulary transition supply will receive the same cost sharing that would apply for a non-formulary exception and transition supply for formulary drugs with a UM edit will receive the same cost share as would apply if the UM criteria is met.

7. Processing for LTC Setting
   a. Pharmacy Network and Patient Residence Type Codes
   Transition parameters can vary by network level (or list of networks) through the use of network or pharmacy lists. Therefore, different transition days supply can be accommodated for retail, mail, LTC and/or home infusion providers. The Pharmacy Service Type and Patient Residence Type codes on submitted claims are used to identify the claims as either non-LTC or LTC for purposes of reimbursement and allowed transition days supply.
      i. The values defined as being LTC by Delegated PBM pharmacy network operations are cross-walked internally during RxClaim adjudication to the legacy system value "Patient Location Code" (PLC) 03.
   b. LTC transition cumulative days supply limits are allowed for qualified claims submitted with PLCs designating LTC.
   c. LTC Emergency Supply (ES) is allowed after the transition supply parameters are exhausted for new Beneficiaries and a coverage determination or exception is still pending. Transition supply parameters do not need to be exhausted for renewing Beneficiaries to receive LTC ES. The Part D Transition Fill LTC ES transition policy provides for at least a cumulative 31 days supply, except for brand oral solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36. The Medicaid Transition of Care Emergency Supply is defined by the MMP contract and plan design.
   d. Transition LTC Level of Care Change and LTC Emergency Supply are automated based upon specific POS claim submission rules. Pharmacies are instructed on how to correctly submit qualifying claims via Provider Manual updates and ongoing network communications so that these claims correctly process as transition under applicable LTC transition conditions.

| LTC LEVEL OF CARE CHANGE & LTC EMERGENCY SUPPLY | |
|---|---|
| Description | Transition Days Supply |

| LTC Level of Care Change (LOC) Beneficiary resides in LTC Facility and is a New Patient Admission | |
|---|---|
| • Beneficiary admitted to LTC facility within the past 30 days | • These quantity plan limits may be greater based on the benefit design and will be limited by the amount prescribed<br><br>Applicable to Part D TF and Medicaid TOC<br>• At POS submitted with:<br>   o Submission Clarification Code 420-DK Value "18"<br>   o Patient Location Code identified as LTC<br>• Additional fills as needed are available via manual transition overrides through the Pharmacy Help Desk<br>• Multiple fills allowed to accommodate LOC changes<br>• Only one transition LTC NP is allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan<br>• New Beneficiaries must have transition days supply exhausted, or transition time period expired<br>• For LTC claims, where SCC 18 is applied to the primary side of an STCOB claim to override Refill Too Soon (RTS) (R79, R88) that same override for RTS (R79, R88) will also apply to the secondary side of the transaction.<br><br>Part D TF<br>• Cumulative applicable month's supply, brand oral solids are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36.<br>Medicaid TOC<br>• Requirements are defined by the MMP contract and plan design. |
| LTC Emergency Supply Beneficiary resides in LTC facility | |
| • LTC Emergency Supply (ES) | • These supplies may be greater based on the benefit design and will be limited by the amount prescribed<br><br>Applicable to Part D TF<br>• At POS submitted with:<br>   o Submission Clarification Code 420-DK Value "7"<br>   o Patient Location code identified as LTC<br><br>• POS automated TF LTC ES is set-up to allow one ES every rolling 30 days, limited to one ES per LTC stay. The adjudication logic looks back 30 days starting the |

day after the date of fill.

- LTC ES is allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan a cumulative days supply during a rolling month or New Beneficiaries must have TF day supply exhausted, or TF time period expired, and while an exception or Prior Authorization is pending

Med D TF
- Cumulative 31 days supply, brand oral solids are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36

Medicaid TOC
- Requirements are defined by the MMP contract and plan design.

e. LTC Level of Care Change for Beneficiaries 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 Beneficiaries are allowed access to a refill upon admission or discharge.

LTC LEVEL OF CARE CHANGE & LTC EMERGENCY SUPPLY (FOR PART D TRANSITION FILL ONLY)

REFILL TOO SOON (RTS) & DRUG UTILIZATION REVIEW (DUR) OVERRIDES

| Description | Edit | Reject Code | Point of Sale | Manual Override Available |
|---|---|---|---|---|
| LTC Level of Care Change | RTS/ Plan Option 15 | 79 | Y | Y (if Drug Qualifies as TF, TF Override used) |
| LTC Emergency Supply | RTS/ Plan Option 15 | 79 | N | Y (if Drug Qualifies as TF, TF Override used) |
| LTC Level of Care Change | DUR – Plan Option 30 | 88 | Y | Y (if Drug Qualifies as TF, TF Override used) |
| LTC Emergency Supply | DUR – Plan Option 30 | 88 | N | Y (if Drug Qualifies as TF, TF Override used) |

8. Transition Edits
   a. **Override Edits Not Applied During Transition**
      Transition overrides are not applied at POS, or manually to drugs with dose limits based on maximum FDA labeling, A or B vs. D drugs requiring coverage determination prior to application of transition benefits, or drugs not covered under MMP program benefits, which include drugs that require a medically accepted indication.
      i. **Refill Too Soon (RTS)**
         Automated transition system logic for new and renewing Beneficiaries does not allow an override of RTS (except for LTC Level of Care Change) edits. Instead, reject 79 (RTS) is returned to pharmacies when submitted claims hit this edit.
      ii. **Drug Utilization Review (DUR) Edits**
         Automated TF system logic for new and renewing Beneficiaries does not allow override of

DUR safety edits that are set up to reject at point of sale. Instead, reject 88 (DUR) is returned to pharmacies when submitted claims hit this edit.

iii. **Part A or B Only Drugs (for Part D Transition only)**
Automated TF adjudication logic is not applied to Part A or B only drug claims. All Med A or B 'only' drugs are excluded from TF processes and payment under TF rules and are tagged with an "N" status in the "Med D" status field on the Delegated PBM drug database. Part B only drugs reject using the appropriate reject codes and applicable Current NCPDP Telecommunication Claim Standards structured reject messaging. Part B only claims reject as A5/A6 combo (not D, always B).

iv. **Part A or B vs. Part D (A or B vs. D) (for Part D Transition only)**
Part A or B vs. D drugs are not provided a Part D TF to determine the appropriate Part A or B vs. D coverage. A determination is needed to identify the correct coverage of the drug. Part A or B vs. D drugs reject using the appropriate reject codes and applicable current NCPDP Telecommunication Claim Standards structured reject messaging. The Beneficiary, prescribing physician, or pharmacy is informed to call Delegated PBM for a clinical review to determine the applicable coverage. In the RxClaim adjudication system, Part A or B vs. D drugs are set up with an identifier flag in the RxClaim Prior Authorization table. The identifier flag specifies that a drug is classified as a Part A or B vs. D drug. Part A or B vs. D claims reject with A3 (This Product May Be Covered Under Hospice – Medicare A); A4 (This Product May Be Covered Under The Medicare-B Bundled Payment To An ESRD Dialysis Facility); A5 (Not Covered Under Part D Law); or A6 (This Product/Service May Be Covered Under Medicare Part B. In the reject messaging of these drug claims, Plan-level phone numbers are provided to assist with contacting the Plan for a determination if needed. If Part A or B vs. D determinations are delegated to Delegated PBM; a determination of the correct coverage will be made. If a formulary drug is covered by Part D, a PA is entered into the RxClaim system to allow the claim to pay under the Beneficiary's Part D coverage. If a non-formulary drug is covered by Part D, the claim is evaluated to determine if it is Transition Fill eligible. If the claim is Transition Fill eligible, then a Transition Fill is provided and the Beneficiary receives the appropriate Transition Fill notification.

v. **Excluded Drugs-not covered by CMS or the state under MMP program benefits**
CMS requires some drugs to be reviewed to determine the Part D drug status. These drugs will require a medically accepted indication based on the FDA approved label or the CMS approved compendia in determining if it is eligible for Part D coverage. Beneficiaries can request a formulary exception for these excluded Part D drugs. Drugs will only be approved for Beneficiaries who provide the diagnosis demonstrating that the drug is prescribed for a medically accepted indication. Beneficiaries who have a coverage determination (Prior Authorization or formulary exception) denied, will receive a denial letter indicating their drug is not a Part D drug. Beneficiaries will have the right to appeal the decision. If the drug is determined to be for a medically accepted indication and so a Part D drug, but any additional utilization management criteria are not met, then the claim is reviewed for TF eligibility and a PA is entered if appropriate.

Excluded drugs may reject for the following reasons: For Medicaid TOC, the exception process and letters are defined by the MMP contract and plan design.
1. Formulary drugs will reject for Prior Authorization (PA) required (R75).
2. Non-formulary drugs will reject as non-formulary (R70).

b. **Transition-Eligible Edits**

MMP transition days supply and time parameters are applied to submitted claims for:
- Non-formulary Part D Drugs
- Non-formulary Medicaid benefit drugs
- Formulary drugs with Prior Authorization, step therapy, QL (quantity vs. time, daily dose or age edits). Transition logic may or may not be applied, according to the Sponsor's benefit design, in situations where there is a maximum FDA labeled dosage that should not be exceeded for safety reasons. The following is the order of processing for drugs to which edits are applied: step therapy; Prior Authorization; Quantity Limits (including daily dose and age).

The unique types of transition conditions are listed below.

i. **Non-formulary (NF)**
Drugs that are not covered on a closed integrated formulary. NF transition overrides a reject code 70 for NDC Not Covered (Plan reject 70). National Drug Code (NDC).

ii. **Prior Authorization (PA)**
Drugs that are covered on the formulary but require Prior Authorization. PA transition overrides a reject code 75 for Prior Authorization.

iii. **Step Therapy**
Formulary drugs that reject for Step Therapy prerequisites may be eligible for transition. A Step Therapy Transition Fill notice may be generated for this edit. Transition processing allows the Step Therapy reject to be overridden and the claim to process through Step Therapy program logic and post to history appropriately. For some drugs with step therapy edits where the Beneficiary obtained a TF ("grandfathered" or Type 2 ST-PA meaning submitted to CMS as step for new starts to therapy only), the transition itself satisfies the step therapy requirements for that drug. This means that the Beneficiary has already met the step requirements and will be able to continue to obtain future fills of that drug without encountering a reject. In these cases, Step transition letters will not be sent to either Beneficiaries or prescribers. Step TF overrides reject 76/75.

iv. **Approved Quantity Limits (QLs)**
Quantity vs. Time (QvT) or Maximum Daily Dose (DD)
Drug quantity limits are used to establish the allowed amounts for coverage of selected drugs to specified values over a set period of time. For the purposes of the transition process, a quantity limit is considered a type of transition for drugs that require limited supply of a drug to be dispensed based on days supply or allowed quantity across time or maximum doses per day.

a. Drugs that would otherwise reject for quantity limitations when submitted for more than the allowed quantity are eligible for transition processing during the transition time period. Transition system logic allows the quantity limit reject to be overridden and the claim to process through transition program logic and to post to history appropriately. If a claim is not eligible for transition override and rejects for quantity limits (i.e. transition days supply exhausted, or transition time period expired), it will continue to reject according to quantity limit parameters using Reject 76. Transition system logic overrides "quantity over time" edits that are set up to either count continuous fill history across Contract Years (quantity "period to date" Type D set-up), or to count fill history beginning January 1 of each Contract Year. QL/QvT transition overrides the reject code 76.

b. In addition to transition for QL/QvT, transition is available for DD drug edits. DD and QL/QvT edits are mutually exclusive. If both were ever to be set up together on the same plan, transition for the QL/QvT edits takes precedence over the DD TF. DD transition overrides reject 76.

c. For QvT transition and Plan Limitations, a QvT set up on drug NDC (Plan Option 10) and/or GPI (Plan Option 11) will override plan limitations that are set up on Plan Options 26.1 and 26.2, Preferred Formulary. Therefore, when transition is allowed for QvT reasons, the Plan Limitations on 26.1 and 26.2 are also overridden. However, cumulative transition days supply does not override either once used/exhausted.

d. For Part D QL changes, the system will look at the QL edit in history and compare it to the current/active QL edit. If the current QL edit is lower than the history edits, the QL edit is overridden and the claim processes through TF program logic.

v. **Age Edits**
Transition is available for formulary drugs that are set up with Age Edits for safety reasons. Age Edit transition overrides a reject 76.

vi. **AG Reject**
An AG Reject is a claim reject due to a days supply limitation. Claims submitted for more than remaining allowed transition Days Supply return an "AG" reject code and message "Resubmit for Remaining Day Supply of XX" with XX being the number of remaining allowed transition cumulative days supply. The "AG" reject code is returned as the primary reject code unless, per current NCPDP Telecommunication Claim Standards, this reject is required to follow either the ADDINS (additional insurance) and/or Brand/Generic Savings messaging when these apply. AG rejects are returned on both initial claims with no prior transition in history, as well as subsequent submissions when cumulative days transition supply has not been exhausted with previous paid transition(s). When a pharmacy reduces the claim days supply and resubmits, transition-eligible claims process via transition rules.

vii. **Unbreakable Pre-packaged Medications for Part D**
Drugs for which the manufactured packaging cannot be split for the dispensing of a prescription may be considered an unbreakable pre-packaged medication for which the pre-packaged medication days supply may be dispensed. The intent of this logic is to ensure a Beneficiary receives their entire transition days supply (DS) even though the DS exceeds the maximum benefit due to the type of packaging for the drug. This logic will apply if the pre-packaged medication cumulative DS is less than the required benefit, prior to the current fill. If the pre-packaged medication cumulative DS, including the current fill, quantity exceeds the maximum benefit, and the current fill is less than or equal to the quantity of a single package of medication, the TF will pay. If the pre-packaged medication cumulative DS, including the current fill quantity, exceeds the maximum benefit, and the current fill quantity exceeds the quantity of a single package of medication, the pharmacy will be messaged to resubmit for a single package of the medication. The claim will retain the messaging and the rejects associated with the processing.

viii. **Beneficiary Level / Clinical Prior Authorizations (PA)**

Beneficiary level clinical Prior Authorizations will be entered to override all transition-eligible edits. Otherwise, a transition will be allowed for any transition-eligible edit for which the PA has not been entered. When a Beneficiary / clinical PA already exists on the Beneficiary record to override all transition-eligible edits, transition processing is not applicable. Under this condition, claims do not process as transitions and transition letters are not sent to Beneficiaries.

    c. **Processed without TF for Part D**

        i. **Protected Class Drugs (PCD) Logic**
The PCD Logic will pay the claim without applying transition logic according to the plan criteria, if the Sponsor selects this logic.

        ii. **Grandfather Drug Logic**
The Grandfather Drug logic will override the NF, Step and PA edit and pay the claim without TF according to the plan criteria, if the Sponsor selects this logic. TF processing will apply to any TF-eligible edit which the Grandfather Drug logic has not overridden.

        iii. **Type 2 ST-PA Drug Logic**
Type 2 ST-PA Drug edits are edits submitted to CMS as Step for new starts to therapy only. Delegated PBM adjudication logic uses a 108-day minimum look back period for determining new starts. The Type 2 ST-PA Drug Logic will pay the claim without TF logic, according to the plan criteria, if the Sponsor selects this logic. TF processing will apply to any TF-eligible edit which the Type 2 ST-PA Drug Logic has not overridden.

9. Transition Claims History
All history for a drug during the transition time period is counted, regardless of the dispensing pharmacy/network. POS, manually entered, and Beneficiary submitted (paper) claims for retail, mail, Long Term Care, and home infusion networks are counted together to determine the total cumulative days supply for a drug. MMP transition days supply limits are defined as cumulative supplies based on Part D days supply requirements or based on the MMP contract and plan design to ensure that refills for transition-eligible drugs are available when the transition is dispensed at less than the amount written secondary to quantity limits due to safety, or edits based on approved product labeling; the system automatically "counts" prior related transition claims to allow correct transition days supply accumulation parameters to apply.

10. If the distinction cannot be made between a brand-new prescription for an MMP Non-formulary Drug and an ongoing prescription for a MMP Non-formulary Drug at the POS, the transition process is applied to a brand-new prescription for a MMP Non-formulary drug.

    a. Beneficiaries who are new to the plan including: new plan Beneficiaries at the start of a Contract Year; newly eligible Beneficiaries from other coverage; and Beneficiaries who switch from one plan to another after the start of a Contract Year.

    b. Part D Transition Fills are available at POS through transition processing during the Part D TF Window. Medicaid Transition of Care is available at POS through transition processing during the TF Window defined by the MMP contract and plan design.

    c. Additional transition supplies are available on a case-by-case basis through the Pharmacy Help Desk to ensure adequate transition.

    d. The quantity and time plan limits may be greater based on benefit design and will be limited by the amount prescribed.

11. Transition Notices

a. Part D TF - For Sponsors using Delegated PBM to fulfill transition notices, Part D TF letters are sent to Beneficiaries within three (3) business days of the adjudicated TF claim; reasonable and best efforts are also made to identify a current prescriber address/contact information and provide notice of a Part D TF to prescribers to facilitate transitioning of Beneficiaries.  For Part D TF, LTC residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less as required by CMS guidance, the written notice will be provided within 3 business days after adjudication of only the *first* temporary fill.  Part D TF Letters are generated from the Part D TF Claim and Letter Tags which are extracted to the daily Part D TF Letter File.

    i. Part D TF Claim and Letter Tag Indicators Based on TF-eligible Edits

        a. TF Claim Tag:  This is the adjudication system tag applied to the claim when adjudicated under TF system rules.  This tag represents the reason the claim paid under TF processes and what edits were overridden by TF rather than rejecting as otherwise would happen when TF is not available.  These tags can represent either a single TF reason (e.g. Non-formulary, PA, Step, or Qty Limit); or can also represent a combination of TF reasons (e.g. PA with Qty Limit; Non-formulary with Qty Limit, etc.).

        b. TF Letter Tag:  This tag is used to designate the specific TF letter language content for the TF notice to Beneficiaries and prescribers.

        c. TF Combo Tag:  This tag is used to designate the specific TF letter language content for the TF notice to Beneficiaries and prescribers for Sponsors who choose to print a paragraph for each edit that was overridden by TF.

    ii. Daily Part D TF Letter File

        a. Paid TF claims are automatically extracted to a daily TF Claim File.  For every paid TF claim, there is either a corresponding record on the correlated daily TF Letter File, or the record is captured on the daily internal exception file with the reason the record is not included on the TF letter file (example: same day paid/reversed).

        b. The contents of the TF Letter file are used to drive production of the appropriate Beneficiary and prescriber TF letters.

b. Medicaid TOC Notices

    i. For Sponsors using Delegated PBM to fulfill Medicaid TOC notices, Delegated PBM has the ability to create both MMP Beneficiary and prescriber TOC notices.  Sponsors must provide separate letter templates for Beneficiaries and prescribers. Template merge data should include only the fields available on the submission file layout.

    ii. A written transition notice is mailed to the MMP Beneficiary and to the prescriber.

    iii. The Medicaid TOC letter does not require CMS approval.

    iv. The Sponsor submits the approved letter template to the Delegated PBM Account Team.

    v. The Delegated PBM Account Team reviews the submitted template and verifies it meets Delegated PBM print production requirements.

    vi. Letter print fulfillment is tested prior to implementation.

c. For Sponsors not using Delegated PBM to fulfill Medicaid TOC transition notices, a report containing the Medicaid TOC claims will be made available to the Sponsor.

12. For Sponsors using Delegated PBM for coverage determinations, Delegated PBM makes Prior Authorization and exception request forms available upon request to Beneficiaries,

prescribers, pharmacies, and others by a variety of means including mail, fax, email, and with the Sponsor via their plan website. Forms may vary depending on state/MMP regulations.

13. Delegated PBM Part D TF process for new Beneficiaries is applied from the date of enrollment through the TF Window. The Medicaid TOC process for new Beneficiaries is applied depending on the MMP contract and plan design. The enrollment date does not need to be the start of the Contract Year and the transition process may extend across Contract Years where the TF Window extends across Contract Years.

14. [Intentionally left blank to maintain consistent numbering between sections.]

15. Transition extensions can be available for new or existing Beneficiaries, non-LTC or LTC, through the Pharmacy Help Desk or Customer Care. The request is reviewed for the following and processed according to Sponsor instructions:
    a. Outside standard Transition days supply or time period parameters
    b. Transition parameters have been reached and Beneficiary is still pending an exception/coverage determination decision

16. Transition for Current Beneficiaries
    a. Renewing Beneficiaries
        i. Renewing Beneficiary - transition fills are available to renewing Beneficiaries who are impacted by a negative formulary change during the TF Window.
            1. Incoming claims for Beneficiaries within their renewing Beneficiary transition window will be evaluated to determine if the drug being requested has been impacted by a negative formulary change.
            2. Negative formulary changes are evaluated through an adjudication process that compares the current formulary edits for the drug being requested to the historical formulary edits previously implemented for the drug.
            3. Negative formulary change evaluation will be performed upon adjudication at the POS.
        ii. Renewing Beneficiaries need to have a history of utilization of the Non-formulary MMP Drug(s). History of utilization is based on the following criteria:
            1. History look back from current date of fill, specified as number of days in the plan set-up, to identify the most recent qualifying history claim
            2. Non-formulary MMP Drug GPI match level specified in the plan set-up
        iii. Beneficiary's clinical Prior Authorization(s) have not already been effectuated.
        iv. For instances where the Beneficiary receives a partial Part D Transition Fill, the system logic will ensure that a renewing Beneficiary's remaining days supply is Transition Fill eligible during the TF Window.
    b. The following processes are options Sponsors may request Delegated PBM to implement for renewing Beneficiaries:
        i. Use the ANOC as advance notice of any formulary changes.
        ii. Prospectively work to educate and transition current Beneficiaries on medications that will no longer be on the formulary in the new Contract Year or that will require Prior Authorization, step therapy or quantity limit utilization management edits in the new Contract Year.
        iii. Encourage processing of formulary exceptions/Prior Authorizations prior to January 1 of a new Contract Year.
        iv. Consistent with the transition process provided to new Beneficiaries, Delegated PBM provides Part D transition fills during the first 90 days of the Contract Year or greater

as specified by MMP, to renewing Beneficiaries with history of utilization of impacted drugs when those Beneficiaries have not been transitioned to a therapeutically equivalent formulary drug; or for whom formulary exceptions/Prior Authorizations are not processed prior to the new Contract Year.  This applies to all renewing Beneficiaries including those residing in Long Term Care facilities. The transition process for Non-Formulary Medicaid benefit drugs will apply according to the Sponsor's MMP contract and plan design.

    c. For Sponsors using the Delegated PBM Pharmacy Help Desk, the Delegated PBM Pharmacy Help Desk is instructed to provide transition supplies per Sponsor's plan design to renewing Beneficiaries who were on medications in the prior Contract Year that are Non-formulary.  For Sponsors using Part D Service Customer Care, on a case-by-case basis, Delegated PBM Customer Care may provide extensions per Sponsor's instructions to accommodate Beneficiaries who continue to await resolution of a pending Prior Authorization or exception requests.

17. Monitoring and Reporting

    a. Part D TF program performance monitoring and reporting includes the production and ongoing review of the items below:

        i. <u>TF Claim Extract Control and Exception Reporting</u> (internal monitoring report) These reports serve as internal controls to confirm that all paid TF claim records are extracted to the daily TF extract file, which is used to produce TF letters or to the Exception file.

        ii. <u>TF Letter Print Quality Control Reviews</u> (internal monitoring) TF Letter Print Quality Control Reviews are used by print fulfillment to validate letter print quality and reliability of printing merge process when changes are made to the templates or process.

        iii. <u>TF Response File</u> (internal monitoring file) This file serves to confirm that for every valid TF record received from adjudication, there is a corresponding TF letter printed/mailed or distributed by other approved method.

        iv. <u>TF Letter Turn-Around-Time (TAT) Reports</u>  (internal and Sponsor monitoring report) These reports track the days between paid TF claims and date TF letters are provided to Beneficiaries.  They are used to monitor adherence with requirements to send Beneficiary TF letters within three (3) business days of the adjudicated TF.

        v. <u>Paid TF Claim File</u> (internal and Sponsor monitoring report) This file supports monitoring of the paid TFs to validate that the claims should have paid under TF rules and that the correct TF tags are applied during adjudication.

        vi. <u>Rejected Claim File</u> (internal and Sponsor monitoring file) Daily Rejected claim reports are produced and reviewed for monitoring of rejected claims to validate that these should not instead have paid under TF rules.

        vii. <u>TF Mock and Test Claims</u> RxClaim maintains the ability to process mock TF claims on demand in support of claims testing.  This allows the Pharmacy Help Desk and Customer Care Services to run claims for confirmation of associated costs, co-payments, and how "live" claims would process and pay under TF.  "Paid" mock TF claims return the standard paid TF messaging as returned on POS claims.

b. Medicaid TOC program performance monitoring and reporting includes the production and ongoing review of the items below:
   i. A Sponsor specific report identifying Medicaid TOC Claims can be generated by the Delegated PBM Account Teams upon request.
   ii. Actual letter proofs, as well as mailing counts and dates, are available upon request.