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

1. **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.
2. **Applicable Month's Supply**: CMS required transition supply, as a minimum (unless prescriptions are written for fewer days); the supply is determined as the number of days submitted for the Plan Benefit Package (PBP)'s applicable month's supply submitted to CMS for the relevant plan year. CMS approval determines the approved month's supply for Beneficiaries in both the non-LTC and LTC settings. Multiple fills up to a total approved month's supply are allowed to accommodate fills for amounts less than prescribed.
3. **Beneficiary**: An individual enrolled in a Delegated PBM Client Medicare Part D Plan, also known as an Enrollee or Member.
4. **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.
5. **CMS:** U.S. Centers for Medicare and Medicaid Services.
6. **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.
7. Delegated PBM **®:** Delegated PBM and each of its subsidiaries and affiliates.
8. **DUR: Drug Utilization Review (DUR):** An analysis of drug usage prescribing intended to ensure clinically appropriate drug therapy and quality of patient care; can be conducted concurrently (between the time the prescription is written and therapy begins), retrospectively (after medication is dispensed), and prospectively (before drugs are prescribed to influence future usage patterns).
9. **Food and Drug Administration (FDA):** The U.S. Food and Drug Administration (FDA) is the government agency responsible for reviewing, approving, and regulating medical products, including pharmaceutical drugs and medical devices.
10. **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.
11. **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.

12. **Long-term Care (LTC):** A variety of services that help people with health or personal needs and activities of daily living over a period of time. Long-term care can be provided at home, in the community, or in various types of facilities, including nursing homes and assisted living facilities. Most long-term care is custodial care.
13. **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.
14. **Low Income Subsidy (LIS):** The program administered by the Social Security Administration (SSA) to subsidize premiums and cost sharing for qualified beneficiaries (i.e., Extra Help).
15. **Medicare Part D (Part D):** An optional voluntary benefit available to all beneficiaries with Medicare that is run by private companies that contract with Medicare. The program provides outpatient drug coverage and requires beneficiaries to pay a monthly premium.
16. **MME:** Morphine Milligram Equivalent
17. **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.
18. **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 pharmacy industry, some of which have been adopted as Health Insurance Portability and Accountability Act (HIPAA) standards.
19. **National Drug Code (NDC):** The National Drug Code is a unique, 3-segment numeric identifier assigned to each medication listed under Section 510 of the US Federal Food, Drug, and Cosmetic Act.
20. **Non-formulary Drugs**: This means: (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, step therapy, or approved quantity limits lower than the Beneficiary's current dose, under a Sponsor's utilization management rules.
21. **Non-Long-Term Care:** Describes Retail, Mail and Home Infusion facilities.
22. **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.
23. **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.
24. **Patient Location Code (PLC):** RxClaim adjudication legacy system value that crosswalks from the Pharmacy Service Type and Patient Residence Type Code.
25. **Patient Residence Type (PR):** Pharmacies collect and record the patient residence at point of sale on the claim.
26. **PCD:** Protected Class Drug.
27. **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, upon the type of service performed.

28. **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.
29. **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.
30. **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.
31. **RxClaim:** Delegated PBM information technology system that serves to process and adjudicate Part D claims; otherwise known as the "system," "platform," or "system platform."
32. **Sponsor:** A Part D Sponsor that contracts with Delegated PBM for pharmacy benefit management services including implementation of its transition process. Also known as the Plan or Plan Sponsor or Client. Sponsor is KS PLAN ADMINISTRATORS, L.L.C.
33. **Submission Clarification Code (SCC):** NCPDP data element indicating that the pharmacist is clarifying the claim submission.
34. **TF Window:** The Beneficiary Transition Fill window is the Sponsor specified number of days (minimum of 90 days) during which Beneficiary transition benefits apply.
35. **Transition Fill - Medicare (TF):** A temporary supply of a Part D covered drug per CMS Part D requirements.

PROCEDURES

1. The Sponsor's TF 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 plan following the annual coordinated election period
        ii. Newly eligible Medicare Beneficiaries from other coverage
        iii. Beneficiaries who switch from another Part D Plan after the start of a Contract Year
        iv. Current Beneficiaries affected by negative formulary changes (including new utilization management requirements)
        v. Beneficiaries residing in LTC facilities
    b. Transition supply limits are defined as cumulative days supplies calculated on Generic Product Identifier and are not based on number of fills.
    c. Transition-eligible claims submitted for LICS III Beneficiaries are processed according to the 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 Med D TF 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 Drugs are to obtain the Sponsor's P&T Committee approved formulary and UM edits, and code into the adjudication system to identify the TF eligible claim at POS so that it can 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 and procedures ensure Beneficiaries have access to processes for medical review of Non-formulary 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/ are 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 fill POS messaging to pharmacies applies as follows:
   a. The Delegated PBM adjudication system automatically processes and pays transition fill-eligible claims and transmits POS messaging that the claims are paid under transition fill rules.
   b. Transition fill 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 fill-specific code for transition fill-eligible claims to pay.
   c. Transition fill processing applies to both new and ongoing prescriptions at POS and through the Pharmacy Help Desk for Beneficiaries who are new to plan.
   d. Communication and educational outreach to network pharmacies is ongoing throughout the year to provide information and instructions regarding transition fill policies and claim processing. At least annually, and more often as needed, transition fill pharmacy communications are distributed through the pharmacy network department.
5. Transition Fill 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 fill-eligible claims and transmits POS messaging that the claims are paid under Transition Fill rules for up to a cumulative applicable month's supply.
   b. Pharmacies are not required to either submit, or resubmit a PAMC, or other transition fill-specific code for transition fill-eligible claims to adjudicate and pay.
   c. Transition fills are available at POS through this functionality within the first 90 days of enrollment, beginning on the enrollment effective date.
   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
For non-LTC residents, an early refill edit will not be used to limit appropriate and necessary access to a transition fill. A transition fill may be provided automatically at POS, if the adjudication process indicates a Level of Care change from LTC to non-LTC with an early refill edit. Otherwise, the pharmacy will call the Delegated PBM Pharmacy Help Desk in order to obtain an override to submit a Level of Care transition fill request.

6. Delegated PBM will establish the cost-sharing per the Sponsor's plan design.
   a. Cost-sharing for drugs supplied as a transition fill is set by statute for low-income subsidy (LIS) Beneficiaries.
   b. For non-LIS Beneficiaries:
      i. non-formulary transition supply will receive the same cost share as would apply if a non-formulary exception was applied
      ii. transition supply for formulary drugs with a utilization management edit will receive the same cost share as would apply if the utilization management criteria is met
7. Long-term Care Processing
   For LTC transition fills, the Delegated PBM adjudication system automatically processes and pays transition fill-eligible LTC claims and transmits POS messaging that these are paid under Transition Fill. LTC transition fills are allowed a cumulative applicable month's supply, except for oral brand solids which are limited to 14 day fills with exceptions as required by CMS guidance, unless submitted with a submission clarification code (SCC) of 21-36. SCC codes 21-36 indicate LTC dispensing of varying days supply. 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. 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 fill-specific code for transition fill-eligible claims to adjudicate and pay.
   a. LTC Transition Fill Emergency Supplies (ES)
      i. To accommodate emergency fills for LTC residents after either the new or renewing TF supply has been exhausted, exceeded 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 Transition Fills are allowed up to a cumulative 31 days supply except for oral brand 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 or exceeded the TF new or renewing TF supply and/or being outside the TF Window.
      ii. LTC ES is allowed, per calendar day, per Beneficiary, per drug, per pharmacy, per plan, for the cumulative days supply during a rolling month, based on benefit design.
      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 LTC residents, an SCC is submitted by the pharmacy to allow transition fills and to override transition fill eligible rejects, Refill Too Soon rejects and certain DUR service rejects for new admissions. Level of Care Transition Fills are allowed up to an applicable month's supply except for oral brand solids which are limited to 14 day

fills with exceptions as required by CMS guidance, unless submitted with an SCC 21-36. These drug claims would otherwise reject for being Non-formulary or formulary with utilization management edits.

ii. Level of Care Transition Fills are allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan for a cumulative days supply within the LTC LOC benefit.

iii. For all Beneficiaries who experience a Level of Care Change, if a dose change results in an "early refill", Refill Too Soon rejects and certain DUR service rejects, 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.

8. Utilization Management Edits Not TF Eligible and TF Eligible Step Therapy and Prior Authorization processing
   a. Delegated PBM codes the following utilization management edits on drugs such that transition fill 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 Part D 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, and age alerts are set up to reject.

   TF eligible 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.
   b. For DUR edits that are based on an FDA maximum recommended daily dose, Transition Fill claims which are dispensed at less than the prescribed amount due to this edit are allowed refills during the TF Window.
   c. Delegated PBM TF cumulative days supply accumulates at the drug GPI 14 level by Beneficiary and across plan (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 Non-formulary Drug and an ongoing prescription for a 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 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.

b. For LTC TF for oral brand solids limited to a 14 days supply, a TF notice will be sent only after the *first* temporary fill.
c. The notice identifies the:
    i. explanation of the temporary nature of the transition supply provided to the Beneficiary
    ii. instructions for working with Delegated PBM and prescriber to satisfy utilization management requirements or to identify therapeutically equivalent and appropriate formulary alternatives
    iii. an explanation of the Beneficiary's right to request a formulary exception
    iv. a description of the procedures for requesting a formulary exception
d. Delegated PBM supports use of the current CMS "Model Part D Transition Notice" for notification to Beneficiaries of the reasons for their 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 transition fill notice is produced. The content of this notice is based on the content of the Beneficiary 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
    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 variety of means including by e-mail, mail, fax, and via forms posted on Delegated PBM websites.
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. 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.
15. Consistent with the transition fill process provided to new Beneficiaries, Delegated PBM provides transition fills to renewing Beneficiaries during the TF Window of the Contract Year 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. This applies at POS to all renewing Beneficiaries including those residing in LTC facilities.
    a. Renewing Beneficiary Transition Fills are available to all Beneficiaries during the TF Window who are impacted by a negative formulary change.

Renewing Beneficiaries need to have a history of utilization of the drug for which coverage is being requested.

b. For these Beneficiaries, the Delegated PBM adjudication system automatically processes and pays transition fill-eligible claims and transmits POS messaging that these are paid under transition fill 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 PAMC, or other transition fill-specific code for transition fill-eligible claims to adjudicate and pay.
d. The quantity and time plan limits may be greater based on benefit design and will be limited by the amount prescribed.

17. Transition Fill Program Monitoring & Reporting
    a. Transition fill processes are monitored both across and within each program area that has responsibility for TF processes. TF program monitoring is both quantitative and qualitative.
    b. Transition claim adjudication data are used to produce standard paid TF Claim and rejected claim reports for quantitative program monitoring. Program performance monitoring includes reporting and monitoring of all TF types: new and renewing Beneficiary TF; and Level of Care Change and LTC Emergency Supply TF.
    c. Support for and Response to Audit and Other Data Requests
        i. Audit requests for transition fill data from CMS or other appropriate entities are responded to within the time period designated in the request; or as soon as reasonably feasible, whichever is most appropriate per the requestor.
        ii. Non-urgent requests for transition fill data are responded to within ten business days. Other response times are available on case-by-case, as needed, basis.

EXHIBITS/APPENDICES

N/A