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Clover Health

Purpose: This policy and procedure describes the operational process used by the delegated PBM to effectuate the formulary transition plan for Clover Health to satisfy Centers for Medicare and Medicaid Services (CMS) requirements for Medicare Part D.

Scope: This policy applies to all members of Clover Health Medicare Advantage product.

Policy:

The Delegated PBM transition fill policies are as follows:

1. Delegated PBM implements and maintains an appropriate transition process, as approved by CMS and consistent with CMS 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 plan: (a.) new Beneficiaries enrolled into the plan following the annual coordinated election period; (b.) newly eligible Medicare 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.
3. The transition policy will apply to Non-formulary 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 approved quantity limits lower than the Beneficiary's current dose under a Sponsor's utilization management rules. The transition process allows for medical review of Non-formulary Drug requests, and when appropriate, a process for switching new Part D Plan Beneficiaries to therapeutically appropriate formulary alternatives failing an affirmative medical

necessity determination. **For 2022, Clover Health is delegating formulary management to Delegated PBM**, the delegated PBM P&T committee reviews 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. 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.

4. Delegated PBM will have systems capabilities that allow Delegated PBM to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of a Beneficiary, as well as, to allow the Sponsor 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. Delegated PBM Transition Fill (TF) processing and coding applies point-of-sale (POS) messaging to pharmacies.
5. Delegated PBM transition process will apply in the non-LTC setting such that the transition policy provides for at least a one-time, temporary 30-day fill, with multiple fills up to a cumulative 30 days supply allowed to accommodate fills for amounts less than prescribed, anytime during the first 90 days of a Beneficiary's enrollment in a plan, beginning on the Beneficiary's effective date of coverage. These quantity and time plan limits may be greater based on the Sponsor's benefit design and will be limited by the amount prescribed. For 2022, Clover Health's plan set up allows a month's supply of 30 within the 90 day TF Window.
6. 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 eligible Beneficiaries:
   a. Non-formulary Part D drugs transition supply will receive the same cost sharing that would apply for a non-formulary drugs approved through a formulary exception in accordance with 42 CFR §423.578(b).
   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. Delegated PBM 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 multiple fills allowed to provide up to a total of a month's supply of medication if needed during the first 90 days of a Beneficiary's enrollment in a plan, 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 an LTC facility, early refill edits will not be used to limit appropriate and necessary access to their Part D benefit, and such Beneficiaries will be allowed to access a refill upon admission or discharge. For 2021, Clover Health's

plan set up allows a month's supply of 31 within 90 day TF Window for LTC and New Patient/Level of Care Change. LTC Emergency Supply allows a 31 day supply; LTC Emergency Supply is allowed per rolling 30 days.

8. 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 Drug if it cannot make the distinction between a brand-new prescription for a Non-formulary Drug and an ongoing prescription for a Non-formulary Drug at POS.
11. Delegated PBM will fulfill transition notices, Delegated PBM will send written notice via U.S first class mail to Beneficiary within three business days of adjudication of a temporary transition fill. The notice will include (a.) an explanation of the temporary nature of the transition supply an Beneficiary has received; (b.) instructions for working with the Plan Sponsor and the Beneficiary's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan'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 long-term care 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. Delegated PBM will use the Transition Notice provided by the Sponsor. Sponsor is responsible for obtaining CMS approval for the Notice submitted using the CMS model Transition Notice via the file-and-use process 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 TF 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. For 2022, Clover Health is using Delegated PBM to fulfill transition notices.
12. Clover Health is using Delegated PBM for coverage determinations, Delegated PBM will make available prior authorization or exceptions 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 2022, Clover Health is using Delegated PBM for coverage determination.
13. Delegated PBM will extend its 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 will make 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. Delegated PBM will provide a process for Beneficiaries to receive necessary Part D 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 2022, Clover Health 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. Clover Health's 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-required reporting, as well as the ability to respond to ad hoc requests for: (a.) denied claim reports; and (b.) paid TF claim reports for new and renewing Beneficiaries. It will also maintain the ability to support test TF claim processing in response to ad hoc requests and will regularly review and audit TF program data and system operations to monitor adherence with Part D Transition Fill requirements.

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 Sponsor's 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:** 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:** Clover Health's pharmacy benefit manager.
8. **DUR:** Drug Utilization Review that does not allow override of select DUR safety edits which are set up to reject at point of sale.
9. **Employee:** Any full-time, part-time, temporary, or casual employee of Delegated PBM, including, but not limited to, interns and externs employed by Delegated PBM.

10. **Food and Drug Administration (FDA):** A federal agency of the U.S. Department of Health and Human Services. This agency is responsible for monitoring of trading and safety standards in the food and drug industries.
11. **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.
12. **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.
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):** Subsidized premiums, deductibles, and/or copayments for which Eligible beneficiaries may be qualified. Also referred to as Extra Help.
15. **Medicare Part D (Part D):** Medicare Prescription drug benefit under Part D of the Social Security Act.
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 retail 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.
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 CLOVER HEALTH.**
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.

Procedure:

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) across Contract year
     v. Beneficiaries residing in LTC facilities
   - **b.** Transition fill supply limits are defined as cumulative days supplies calculated on Generic Product Identifier (GPI) 14 and are not based on number of fills. See Implementation Statement 16.a for additional information.
   - **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. Clover Health 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. Clover Health delegates 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 30 days 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 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 sharing that would apply for a non-formulary exception
  - 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 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 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 31 days 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 days supply has been exhausted or the transition fill (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 31 days cumulative 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 daily dose less than FDA maximum labeled dose, or age edits secondary to Beneficiaries having exhausted TF new or renewing TF days 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 30 days based on the 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 and Refill Too Soon rejects for new admissions. Level of Care Transition Fills are allowed up to a 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 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.

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 TF eligible claim for a LICS III Beneficiary with the appropriate pharmacy submitted codes.

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

8. Utilization management edits not TF Eligible and 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, cumulative morphine equivalent (MME), drug interaction, 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 a 30 days 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. Clover Health is 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

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 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 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 fills, to renewing Beneficiaries during the TF Window of the Contract Year 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 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 across Contract Years. 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 New Patient Admission 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.

IMPLEMENTATION STATEMENT

The following is a summary statement for how eligible claims process under TF 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 TF adjudication system rules is to ensure pharmacies are able to resolve and override TF-eligible edits at POS toward the goal of ensuring Beneficiary access to medications per Part D requirements and guidance.

1. TF Adjudication System ensures that:

a. TF-eligible claims for new and ongoing prescriptions automatically adjudicate upon submission at POS for:

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) from one Contract Year to the next

v. Beneficiaries residing in LTC facilities

b. Transition fill 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 TF eligibility start date is provided by the Sponsor and based on plan design. TF logic is not invoked if a claim exceeds either TF Window or cumulative days supply parameters based on Beneficiary eligibility.

d. TF processing allows for transition supplies of different drug strengths.

TF benefits (including Cumulative Days Supply) are set up based on Drug Generic Product Identifier (GPI) 14 to allow TF processing of different strengths of a drug under TF system rules. This ensures that a Beneficiary taking a drug with one strength is able to receive TF for same drug/different strength if they present with a new prescription within TF-eligible time period.

e. For Beneficiaries who are new to plan, renewing Beneficiaries during the TF window, and for LTC new patient admissions and emergency supplies, TF for dosage escalation is allowed, as appropriate, by manual override via the Delegated PBM Pharmacy Help Desk.

f. Med D Drugs only allowed for TF.

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

g. Multi-Ingredient Compounds processed for 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). Only Non-formulary drugs will process under MIC TF rules. Step therapy protocols are bypassed for MIC drugs and these claims are paid outside of TF. QvT, daily dose and age edits may be bypassed for MIC drugs and claims paid outside of TF based on benefit design set-up. Since MICs 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.)

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 set-up 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:
    1. If the most expensive ingredient is a formulary drug, then all Part D ingredients in the MIC pay at contracted rates.
    2. 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.
    3. If the most expensive ingredient is not eligible for TF, the entire MIC will reject / not pay as TF.

For 2022, Clover Health will process MIC claims all as Non-formulary. The following edits will not be bypassed for MIC claims: Step, QvT, daily dose and age.

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

3. Claims for Non-formulary Drugs are eligible for TF processing.
   a. Generic Drug Launch
      i. Brand Drug retained as formulary when generic released: In the event of the launch of a new generic drug, the Sponsor elects whether to retain the brand on the formulary and not to add the generic to the formulary. A Beneficiary with the equivalent brand drug in the look back history will not be eligible for a transition fill of the generic with the same formulation, if the Sponsor elects not to offer the TF. The pharmacy will be messaged to dispense the brand. The brand would be available without the need for a TF. If a Beneficiary is currently taking a brand drug, a transition fill for the brand drug with a formulary change will be provided to allow Beneficiary sufficient time to work with the prescriber to obtain 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.
      ii. 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 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 TF-specific codes for a TF-eligible claim to adjudicate.

   a. POS Pharmacy Provider Notification
      i. Pharmacies are notified at POS that claims have paid under TF rules, which is intended to assist pharmacies with discussing next steps with Beneficiaries.
      ii. TF processing information and communications are sent to all network pharmacies. The TF 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 document that is 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 Beneficiary's TF availability, process and rights for requesting prior authorization and/or exception, and how to submit an automated TF request.
      iv. Auto-pay of TF-Eligible Claims
      When submitted claims are eligible for payment under TF rules, RxClaim adjudication system logic applies the TF PAMC 22223333444 to the claim, tags the claim as a paid TF, and returns the below 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. The TF-related codes and messaging returned to pharmacies on paid TF claims is compliant with Current NCPDP Telecommunication Claim Standards. In accordance with these standards, the "Paid under transition fill" messaging follows the ADDINS (additional insurance) and Brand/Generic Savings messaging when these apply. Otherwise, the "Paid under transition fill" is returned as the first message on paid TF claims. Non-TF eligible claims are rejected and are not paid under TF rules.

"Paid under transition fill. Non-formulary."
"Paid under transition fill. PA required."
"Paid under transition fill. Other reject." (Note: This includes Step, QvT, Daily Dose and Age requirements)

In addition to the POS messaging above, and in accordance with Current NCPDP Telecommunication Claim Standards, the below approval message codes are also returned on TF paid claims.

TF APPROVAL MESSAGE CODES

NCPDP Pharmacy Approval Message Code	TF Condition
005	TF claim is paid during transition period but required a prior authorization
006	TF claim is paid during transition period and was considered Non-formulary
007	TF claim is paid during transition period due to any other circumstance
009	TF claim is paid via an emergency fill scenario but required a prior authorization
010	TF claim is paid via an emergency fill scenario and was considered Non-formulary
011	TF claim is paid via an emergency fill scenario due to any other circumstance

013	TF claim is paid via a level of care change scenario but required a prior authorization
014	TF claim is paid via a level of care change scenario and was considered Non-formulary
015	TF claim is paid via a level of care change scenario due to any other circumstance

b. There are conditions under which it may be necessary for the Delegated PBM PHD or CC to enter a manual TF 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 TF period expires, or the TF cumulative days supply exhausted

iii. TF for dosage increase is needed

c. When manually entered with the TF PAMC, these TF overrides are adjudicated and tagged via the same processes as automated POS TF's. The same "Paid under transition fill…" messaging is returned to Pharmacies on manual TF overrides as returned on automated paid TF claims. TF letters are produced and sent to Beneficiary for manual TF overrides same as POS overrides.

5. TF Days Supply & Time Period Parameters (and LTC Days Supply for Statement 7)

a.

Description	TF 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 • Non-LTC: 30 cumulative days supply within first 90 days in the plan; multiple fills up to a cumulative applicable month's supply are allowed to accommodate fills for amounts less than prescribed. • LTC: cumulative 31 days supply within first 90 days in the plan, oral brand 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 31 days supply are allowed to accommodate fills for amounts less than prescribed / first 90 days
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 • Non-LTC: up to a 30 days supply; multiple fills up to a cumulative 30 days supply are allowed to accommodate fills for amounts less than prescribed. • TF available at POS if identified through adjudication, otherwise through manual override via Pharmacy Help Desk on case-by-case basis
New and Renewing TF Extension	
• New or Existing Beneficiaries • Outside standard TF days supply or time period parameters • TF parameters have been reached and Beneficiary is still pending exception/coverage determination decision	• These plan limits will be limited by the amount prescribed • Non-LTC: Per Sponsor's plan design, via manual override, additional as needed as long as exception or coverage determination decision is pending • LTC: per Sponsor's plan design, via manual override, additional as needed as long as exception or coverage determination decision pending

b. Non-LTC Resident Level of Care Change

i. For non-LTC residents, a transition fill 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 may call the Delegated PBM Pharmacy Help Desk in order to obtain an override to submit a Level of Care transition fill 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. The non-LTC residents are allowed up to a 30 days supply (or greater based on benefit design); multiple fills up to a cumulative 30 days supply are allowed to accommodate fills for amounts less than prescribed.

6. The adjudication system ensures that cost-sharing applied to TF's for low-income subsidy (LIS) Beneficiaries never exceeds statutory maximum co-pay amounts; and for non-LIS Beneficiaries, cost-sharing is based on one of the plan's approved cost-sharing tiers and is consistent with that charged for a Non-formulary drugs approved under a coverage exception. 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

TF parameters can vary by network level (or list of networks) through the use of network or pharmacy lists. Therefore, different TF days supply can be accommodated for Retail, Mail, Long-term Care and/or Home Infusion providers. The Pharmacy Service Type and Patient Residence Type codes on submitted claims are used to identify the submitting pharmacy as either non-LTC or LTC for purposes of reimbursement and allowed TF days supply.

i. The values defined as being LTC pharmacy 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 TF cumulative days supply limits are allowed for qualified claims submitted with pharmacy service and patient residence types designating LTC.

i. If the Patient is designated LICS III in addition to the LTC Pharmacy Service Type and LTC Patient Residence Type on the qualified claim, the LTC TF benefit is applied.

c. LTC Emergency Supply (ES) is allowed after the transition supply parameters are exhausted and a coverage determination or exception is still pending. The LTC ES transition policy provides for a cumulative 31 days supply, except for oral brand solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36.

d. TF LTC New Patient Admission/ 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 TF under applicable LTC TF conditions.

Description	TF Days Supply
LTC Level of Care Change (LOC) Beneficiary resides in LTC Facility (New Admission)	
• Beneficiary admitted to 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 • Cumulative 31 days supply, except for oral brand solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36 At POS submitted with: • Submission Clarification Code 420-DK Value "18" • Patient Location Code identified as LTC. • Additional fills as needed are available via manual TF overrides through the Pharmacy Help Desk • Multiple fills allowed to accommodate LOC changes • TF LTC LOC is allowed per calendar day, per Beneficiary, per drug, per pharmacy, per plan a cumulative days supply within the defined LTC LOC benefit. • New and renewing Beneficiaries must have TF days supply exhausted, exceeded or the TF time period expired • For LTC claims, where SCC 18 is applied to the primary side of a single transaction coordination of benefit 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. • If LTC LOC benefit is engaged and pays it will count towards the LTC LOC benefit. Remaining non-LTC or LTC TF benefits will still be available through the TF Window. • If the incoming LTC LOC claim days supply exceeds the maximum LTC LOC benefit, the pharmacy will be

	messaged to notify of the remaining non-LTC or LTC TF benefit available through the TF Window.
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 • Cumulative 31 days supply, except for oral brand solids which are limited to 14 days supply with exceptions as required by CMS guidance, unless submitted with an SCC 21-36. At POS submitted with: • Submission Clarification Code 420-DK Value "7" • Patient Location Code identified as LTC. • 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 • New and renewing Beneficiaries must have TF days supply exhausted, or TF time period expired, and while an exception or prior authorization is pending. • If LTC ES benefit is engaged and pays it will count towards the LTC ES benefit. Remaining non-LTC or LTC TF benefits will still be available through the TF Window. • If the incoming LTC ES claim days supply exceeds the maximum LTC ES benefit, the pharmacy will be messaged to notify of the remaining non-LTC or LTC TF benefit available through the TF Window.

e. LTC New Patient Admission or 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 NEW PATIENT & LTC EMERGENCY SUPPLY
REFILL TOO SOON (RTS) & DRUG UTILIZATION REVIEW (DUR) OVERRIDES

Description	Edit	Reject Code	Point of Sale	Manual Override Available
LTC New Patient	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 New Patient	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 Fill Edits

a. Override Edits Not Applied During TF

TF 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 TF benefits, or drugs not covered by CMS under Part D program benefits, which include drugs that require a medically accepted indication.

i. **Refill Too Soon (RTS)**

Automated TF system logic for new and renewing Beneficiaries does not allow override of RTS (except for LTC New Patient Admission or Level of Care Change) edits. Instead, reject 79 (RTS) is returned to pharmacies when submitted claims hit this edit.

ii. **DUR Safety 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 with appropriate instructions when submitted claims hit this edit.

iii. **Part A or B Only Drugs**

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 A or B only drugs reject using the appropriate reject codes and applicable Current NCPDP Telecommunication Claim Standards structured reject messaging.

iv. **Part A or B vs. Part D (A or B vs. D)**

Part A or B vs. D drugs (formulary drugs with a UM edit) are not provided a TF because coverage is available for drugs. A determination is needed to identify what coverage will be applied to 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. This allows the pharmacy or Beneficiary to call Delegated PBM for clinical review to determine coverage. The identifier flag can be set up on the RxClaim Prior Authorization table to specify Med A or B vs. D drugs. Med A or B v. D claims reject as A6 (B vs. D), A5 (Not D, not B. Not covered under Part D Law) or A4 (This Product May Be Covered Under The Medicare- B Bundled Payment To An ESRD Dialysis Facility.), A3 (This Product May Be Covered Under Hospice-Medicare A). Plan-level phone numbers are returned in the reject messaging for formulary drug claims rejecting for A or B vs. D determinations to enable pharmacies to follow-up. Once the determination is made, if a drug is determined to be Part D eligible, a PA is entered. Non-formulary drugs in these categories, as a rule, will not be covered under Part A or B or Part D. Therefore, a TF is provided to allow the enrollee to leave the pharmacy with a temporary supply and work with their prescriber to identify a formulary alternative.

v. Excluded Drugs-not covered by CMS under Part D program benefits

CMS requires some drugs 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 drugs. Drugs will only be approved for Beneficiaries who provide 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:

1. Formulary drugs will reject for prior authorization (PA) required (R75).
2. Non-formulary drugs will reject as non-formulary (R70).

b. TF-Eligible Edits

TF day supply and time parameters are applied to submitted claims for:

- Non-formulary Drugs
- Formulary drugs with prior authorization, step therapy, quantity vs. time, daily dose or age edits. TF logic may or may not be applied, according to Sponsor 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 fill conditions are listed below.

i. Non-formulary (NF)

Drugs that are not covered on a closed formulary. NF TF 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 TF overrides a reject code 75 for Prior Authorization.

iii. Step Therapy

Formulary drugs that reject for Step Therapy prerequisites may be eligible for TF. TF processing allows the Step Therapy reject to be overridden and the claim to process through Step Therapy program logic and post to history appropriately. A Step Therapy transition fill notice may be generated for this edit. For some drugs with step therapy edits where the Beneficiary obtained a TF ("grandfathered" or Type 2 PA meaning submitted to CMS as step for new starts to therapy only), the TF 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 TF Letters are not sent to either Beneficiaries or prescribers. Step TF overrides 608 reject step therapy, alternative drug therapy required based upon Plan Benefit Setup.

iv. Quantity Limits (QL's)

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 TF, a quantity limit is considered a type of transition fill 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.

1. Drugs that would otherwise reject for quantity limitations when submitted for more than the allowed quantity are eligible for transition fill processing during the transition time period. TF system logic allows the quantity limit reject to be overridden and the claim to process through TF program logic and to post to history appropriately. If a claim is not eligible for TF override and rejects for quantity limits (i.e. TF days supply exhausted, or TF time period expired), it will continue to reject according to quantity limit parameters using Reject 76. TF 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 TF overrides the reject code 76.
2. In addition to TF for QL/QvT, TF 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, TF for the QL/QvT edits takes precedence over the DD TF. DD TF overrides reject 76.
3. For QvT TF 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 TF is allowed for QvT reasons, the Plan Limitations on 26.1 and 26.2 are also overridden. However, cumulative TF days supply does not override either once used/exhausted.
4. For 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 edit, the QL edit is overridden and the claim processes through TF program logic.

v. Age Edits

TF is available for formulary drugs that are set up with Age Edits for safety reasons. Age Edit TF 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 TF Days Supply return an "AG" reject code and message "Resubmit for Remaining Day Supply of XX" with XX being the number of remaining allowed TF 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 TF in history, as well as subsequent submissions when cumulative days TF supply have not been exhausted with previous paid TF. When a pharmacy reduces the claim days supply and resubmits, TF-eligible claims process via TF rules.

vii. Unbreakable Pre-packaged Medication Logic

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

c. Processed without TF

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. TF 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. TF days supply limits are defined as cumulative supplies based on Part D days supply requirements to ensure that refills for TF-eligible drugs are available when TF 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 TF claims to allow correct TF days supply accumulation parameters to apply.

10. 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 transition process is applied to a brand-new prescription for a Non-formulary drug.

a. Beneficiaries who are new to plan include: new plan Beneficiaries at the start of 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. Transition fills are available at POS through transition processing during TF Window.
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. Clover Health utilizes Delegated PBM to fulfill transition notices, TF Letters are sent to Beneficiaries within three (3) business days of adjudicated TF claim; reasonable and best efforts are also made to identify a current prescriber address and provide notice of TF to prescribers to facilitate transitioning of Beneficiaries. For long-term care 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. TF Letters are generated from the TF Claim and Letter Tags which are extracted to the daily TF Letter File.

a. TF Claim and Letter Tag Indicators Based on TF-eligible Edits

i. 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.).

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

iii. 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.

b. Daily TF Letter File

i. 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).

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

12. Clover Health utilizes 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.
13. Delegated PBM transition process for new Beneficiaries is applied from the date of enrollment through the TF Window. The enrollment date does not need to be the start of the Contract Year and may extended across Contract Years for Beneficiaries with an effective enrollment date of either November 1 or December 1 or earlier based on the length of the TF Window and who need access to a transition supply for a negative formulary change.
14. [Intentionally left blank to maintain consistent numbering between sections.]

15. TF Extensions are available for New or Existing Beneficiaries, non-LTC or LTC, through the PHD or CC. The request is reviewed for the following and processed according to Sponsor instructions:

a. Outside standard TF days supply or time period parameters

b. TF parameters have been reached and Beneficiary is still pending exception/coverage determination decision

16. Transition for Current Beneficiaries

a. Renewing Beneficiaries need to have a history of utilization of the Non-formulary Drug(s). History utilization requires the following criteria:

i. History look back from current date of fill is specified as 180 days in the plan set-up to identify the most recent qualifying history claim

ii. History look back drug GPI match level specified as GPI 10 in the plan set-up.

iii. History claim(s) for same drug

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 POS.

ii. Beneficiary's clinical prior authorization(s) are not already effectuated

iii. For instances where the Beneficiary receives a partial transition fill, the logic will ensure that the 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 fill process provided to new Beneficiaries, Delegated PBM provides transition fills, to renewing Beneficiaries during the first 90 days of the Contract Year 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.

c. 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. On a case-by-case basis, theDelegated 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. TF program performance monitoring and reporting includes the production and ongoing review of the items below:

a. TF Claim Extract Control and Exception Reporting (delegated PBM 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.

b. TF Letter Print Quality Control Reviews (delegated PBM 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.

c. TF Response File (delegated PBM 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.

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

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

f. Rejected Claim File (delegated PBM 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.

g. TF Mock and Test Claims
RxClaim maintains ability to process Mock TF claims on demand in support of claim testing. These allow 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.

EXHIBITS/APPENDICES

N/A