Signature Advantage, LLC (H2400) CY2020 Medicare Part D Transition Policy

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Effective Date: January 1, 2020

Revision Date: N/A

Version: 1

Policy Purpose:

The purpose of this policy is to describe Sponsor's process for transition (as adopted from and administered by its PBM, PBM) and ensure that continued drug coverage is provided to new and current Part D members. The transition process allows for a temporary supply of drugs and sufficient time for members to work with their health care providers to select a therapeutically appropriate formulary alternative, or to request a formulary exception based on medical necessity. Transition processes will be administered by PBM in a manner that is timely, accurate and compliant with all relevant CMS guidance and requirements as per 42 CFR §423.120(b)(3).

Scope: This policy is necessary with respect to: (1) new enrollees into prescription drug Sponsors following the annual coordinated election period; (2) newly eligible Medicare beneficiaries from other coverage; (3) enrollees who switch from one Sponsor to another after the start of a contract year; (4) current enrollees affected by negative formulary changes across contract years, (5) enrollees residing in long-term care (LTC) facilities. Applicable personnel at PBM and Sponsor comply with the processes and requirements set forth herein. This document is intended to describe processes necessary to meet regulatory requirements as of the effective date above.

Sponsor requires its PBM to provide confirmation that it can meet and properly administer each element of the Transition Policy Attestation. Detailed standard operating procedures, Attestations mapping, and transition policy documents are available and updated at least annually.

Applicability

This Policy and Procedure applies to Signature Advantage, LLC, CMS Contract H2400.

Key Points

Signature Advantage, LLC has sole responsibility for meeting CMS transition policies as outlined in 42 CFR §423.120(b)(3).

Signature Advantage, LLC delegates portions of the transition policy and procedure to Signature Advantage, LLC's Pharmacy Benefit Manager (PBM), EnvisionRx. Key Policy and Procedures outlined below have been adapted from the PBM's internal policy and procedure to reflect their process on behalf of Signature Advantage, LLC. Signature Advantage, LLC. provides oversight of EnvisionRx for delegated activities.

All references to the "Sponsor" refer to Signature Advantage, LLC.

All references to PBM refer to EnvisionRxOptions.

Prior Authorization (PA), Step Therapy (ST), Quantity Limit (QL), Non-formulary Exception (NFE) may be reflected in the policy by abbreviations.

The policy contains Implementation Statement sections which outlines detailed processes of the policy followed by specific Policy Statements.

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1. Implementation Statement Section 1: Processing Transition Requests:

1.1. Days Supply

1.1.1. The transition fill month's days' supply is defined in the applicable Plan Benefit Package, for both the retail and long-term care settings. The Sponsor Benefits retail days' supply is 30 and the Sponsor Benefits long-term care setting days supply is 31. These amounts are applicable to days supply throughout the policy.

1.1.2. Either one month's supply or multiple fills for up to a month's supply is administered.

1.1.3. Unbreakable/Smallest package size drugs will be configured to automatically allow a claim that is dispensed as the smallest package size available and whose day supply calculation based on prescribed directions exceed the day supply limitation set by the Sponsor.

1.2. Non-Formulary Transition Configuration:

1.2.1. The Rx Claim submitted by the pharmacy

1.2.2. The Rx is then sent through a series of Formulary List filters to remove drugs from non-formulary transition consideration such as Medicaid, Enhanced, BVD, and actual formulary drugs. If it hits, then the claim is satisfied and it moves on to the next level of processing.

1.2.3. If it is not part of one of the Formulary filters then the Rx is sent through a series of All Drugs lines setting transition tiers and day supply limitations.

1.2.3.1. The first 2 for exceptions based on level of care changes.

1.2.3.2. Then Smallest package size transition.

1.2.3.3. Then LTC, Assisted Living, and intermediate care.

1.2.3.4. The last line is set up to account for non-LTC.

1.2.4. Transition lines are set up to indicate a specific tier (Set Tier to this → T), where the letter T is equal to the appropriate tier copayment/co-insurance for a non-formulary transitional drug.

1.2.5. Each All Drugs line is set up to also account for the Rx Date in comparison to the member's Start date: *Apply Only If Match during GF days after Mem Start [90].*

1.2.6. Based on the service code submitted and the relation in dates, the Rx will hit the appropriate line and the related actions/handlers will be applied.

1.2.7. If the RX is not part of one of the Formulary filters and the Rx Date is not within the first 90 days of members effective date with the Sponsor, the claim will pass through subsequent CPM's and reject with NCPDP reject code MR, as well as with additional messaging that states "NON-FORMULARY DRUG. TRANSITIONAL PERIOD OVER. USE FORMULARY PRODUCT. Call ###-###-#### or log on to https://envision.promptpa.com to initiate exception request." This additional messaging is located on the 0000 CCYY NONFORM REJ V4 common process modifier.

1.3. Prior Authorization and Step Therapy Transitional

1.3.1. The Rx Claim submitted by the pharmacy

1.3.2. The Prior Authorizations (PA) filters are created on the Sponsor Year 2019 Prior Authorization List Process Modifier that looks at the member's start date.

1.3.3. If the system does not find a GPI match within 90 days of the start date of the member, then the claim hits the filter line and allows the Rx to go thru without requiring a PA.

1.3.4. For Transitional PA and Step Therapy (ST) non-LTC Claims, the member is allowed up to an accumulated one month supply within their first 90 days. This is done with a MISC Handler (handler name = ***TRANSD3***) that is attached to all transitional PA/ST non-LTC claims. This handler allows the member up to a max of 30DS within a non-LTC setting regardless of the number of prescriptions processed.

1.3.4.1. Each fill however is limited to a 30 Day Supply.

1.3.5. For Transitional PA and Step Therapy LTC Claims, the member is allowed up to an accumulated one month supply (31 days) within their first 90 days. This is done with a MISC Handler (handler name = ***TRANSD3LTC***) that is attached to all transitional PA/ST LTC claims.

1.3.6. If the smallest available package size exceeds a 30 Non-LTC/31 LTC day supply, a transition fill for an appropriate days supply that exceeds these limits will be provided. Once outside of the member's initial 90 days, the filter lines will no longer apply and the system will resume with the normal Prior Authorization/Step Therapy functionality if a prior

authorization was not already obtained. (see section titled “CMS Notice of Appeal Rights” for additional information regarding Prior Authorization/Step Therapy functionality outside of members initial 90 days)

1.3.7. If the member’s start date is different than 01/01/2019, the 90 days can refresh from the new start date:

1.3.8. If today the member start date is 4.1.2010, the filters will be active for the script(s) thru 6.30.2010.

1.3.9. Each PA and ST criteria will need 5 lines.

1.3.9.1. **Line 1 of PA logic:**The first line accounts for a LTC service code of 3 (*Apply Only if Service Code [F384:^3]*) and the fact that the member is within the first 90 days of their start date (*Apply Only if Match During GF days after Mem Start [90]*). The MISC Hander **MUST** start with **TRANSD3LTC,** this allows reports to be run that initiate and produce Transitional Letters.

1.3.9.2. **Line 2 of PA logic:** The second line accounts for a LTC service code of 4 (Apply Only if Service Code [F384:^4]) and the fact that the member is within the first 90 days of their start date (Apply Only if Match During GF days after Mem Start [90]).The MISC Hander MUST start with TRANSD331, this allows reports to be run that initiate and produce Transitional Letters.

1.3.9.3. **Line 3 of PA logic:** The third line accounts for a LTC service code of 9 (Apply Only if Service Code [F384:^9]) and the fact that the member is within the first 90 days of their start date (Apply Only If Match during GF days after Mem Start [90]). The MISC Hander MUST start with TRANSD331, this allows reports to be run that initiate and produce Transitional Letters.

1.3.9.4. **Line 4 of PA logic:** The fourth line accounts for non-LTC claims that are within the first 90 days of the member’s start date (*Apply Only if Match During GF days after Mem Start [90]*). The MISC Hander **MUST** start with **TRANSD3,** this allows reports to be run that initiate and produce Transitional Letters.

1.3.9.5. **Line 5 of PA logic:** The fifth line accounts for all claims (regardless of LTC status) that are outside of the first 90 days of the member’s start date. This line provides back a reject 75 with the configured PA messaging. See section titled “CMS Notice of Appeal Rights” for additional information regarding Prior Authorization/Step Therapy functionality outside of members initial 90 days.

1.4. Quantity Limit (QL) Transitional Fills

1.4.1. Quantity limit filters are created on the Sponsor Year 2019 QL Process Modifier (0000 CCYY QL V9) that looks at the member’s start date.

1.4.2. If the system does not find a GPI match within 90 days of the start date of the member, or the claim is equal to or less than the filed QL the claim

hits the appropriate filter line and allows the Rx to go thru without enforcing the filed QL.

1.4.3. For Transitional QL non-LTC Claims, the member is allowed up to an accumulated one month's supply within their first 90 days. This is done with a MISC Handler (handler name = ***QTYTRAND30***) that is attached to all transitional QL non-LTC claims. This handler allows the member up to a max of 30DS within a non-LTC setting regardless of the number of prescriptions processed.

1.4.3.1. Each fill however is limited to a 30 Day Supply.

1.4.4. For Transitional QL LTC Claims, the member is allowed up to an accumulated one month supply (31 days) within their first 90 days. This is done with a MISC Handler (handler name = ***TRANSD3LTC***) that is attached to all transitional LTC claims.

1.4.5. Once outside of the member's initial 90 days, the filter lines will no longer apply and the system will resume enforcing the filed QLs (see section titled "CMS Notice of Appeal Rights" for additional information regarding QL functionality outside of members initial 90 days)

1.4.6. If the member's start date is different than 01/01/2019, the 90 days can refresh from the new start date

1.4.7. If today the member start date is 4.1.2010, the filters will be active for the script(s) thru 6.30.2010.

1.4.8. Each QL criteria will need 6 lines. **Line 1 of the QL logic:**

1.4.8.1. **Line 1 of the QL logic:** The first line accounts for claims submitted with a quantity/day supply that is equal to or less than the filed QL and will allow the Rx to go through without enforcing the filed QL or transition rules.

1.4.8.2. **Line 2 of the QL logic:** The second line accounts for a LTC service code of 3 (Apply Only if Service Code [F384:^3]) and the fact that the member is within the first 90 days of their start date (Apply Only if Transition).

1.4.8.3. **Line 3 of the QL logic:** The third line accounts for a LTC service code of 4 (*Apply Only if Service Code [F384:^4]*) and the fact that the member is within the first 90 days of their start date (*Apply Only if Transition).*

1.4.8.4. **Line 4 of the QL logic:** The fourth line accounts for a LTC service code of 9 (*Apply Only if Service Code [F384:^9]*) and the fact that the member is within the first 90 days of their start date (*Apply Only if Transition).*

1.4.8.5. **Line 5 of the QL logic:** The fifth line accounts for non-LTC claims that are within the first 90 days of the member's start date (*Apply Only if Transition).*

1.4.8.6. **Line 6 of the QL logic:** The sixth line accounts for all claims (regardless of LTC status) that are outside of the first 90 days of the member's start date. This line provides back a reject 9G with the configured PA messaging, if the claim is above the filed quantity limit.

1.5. Transition Across Sponsor Years for Negative Formulary Changes for Current Members Pharmacy Claims Adjudication Detail

1.5.1. For any drugs that become non-formulary from one Sponsor year to the next or require a new step therapy or prior authorization within the new Sponsor year, programming for grandfathering will be configured to allow existing members who had these drugs in their history to get up to an accumulated one month's supply transitional fill within the first 90 days of the benefit year.

1.5.2. A formulary list is created and named 0000 NF GF for the drugs that have become non-formulary or have a new prior authorization or step therapy for the new-year. A formulary list should be created for each type of negative change. These formulary lists become filters within the MPDCD 0000 PARTD PCD & GF V1 process modifier. The filters built within, allow the drugs to be treated as formulary for a transitional fill for any existing member with this drug in their history prior to the new-year.

1.5.3. The tier assigned for non-formulary medications is the Sponsor defined standard benefit, Tier 1 and is indicated on this Common Process Modifier for non-formulary transitional fills along with the accumulated one month's supply only dispensing limits.

1.5.4. The Grandfathering list is attached to a Common Process Modifier with specified rules to allow up to an accumulated one month's supply fill and indicates messaging that this is a transitional fill for the transitional period for these members.

1.5.5. If the system finds a match for a drug on the Grandfathered List within the window or days going back in history (look-back period is 120 days) of the new benefit year or the GF start Date go back in history, then the claim hits the transitional GF PM (filter line) and allows the Rx to go thru.

1.5.6. The drug will have been be flagged as the Sponsor's designated tier on the grandfather formulary list. This will allow the drug to continue processing within the Gross Covered Drug Cost (PPP) and TrOOP amount (PTR) Process Modifiers on the Sponsor and attribute to the PPP (see #2) and PTR (see #3) values for this fill and include it as a PART D covered drug.

1.5.7. When a transitional fill is adjudicated, a transitional letter is generated via a crystal report. This is accomplished by selecting a “Stamp PM Name into Formulary Field” checkbox edit. All claims that are “flagged” by this edit are pulled for transitional letters (see Stamp PM Name into Formulary Field shown below) (#1 D)

1.5.8. Script tags are used to identify the type of transition fill (e.g. Prior Authorization, Step Therapy, Quantity Limit, Non-Formulary Part D drug) as well as LTC or non-LTC. These script tags are included on the crystal report and used to identify the appropriate transition letter language.

1.5.9. Once outside of the member’s initial 90 days, the filter line will no longer apply and the system will resume with the rejection for NON-formulary Drug not covered (rej MR). – also see section titled “CMS Notice of Appeal Rights” for additional information)

1.5.10. Remember, if the member’s history does not go back the allotted window, they are not eligible for this grandfathering fill.

1.5.11. The start date is 1.1.20**, for this rule to look back in history.

1.5.12. This will only allow a 1 time fill within the first 90 days of the benefit year and terms as of 3/31/20**

1.5.13. In the LTC setting, additional transition fills outside of the accumulated one month’s supply automated fill at this time will require the pharmacy to call Customer Service to request additional manual overrides.

1.5.14. In order to obtain additional transition refills for emergency situations or for additional LTC transitional fills that fall outside of the transition or grandfathering period, pharmacies may submit applicable Submission Clarification Codes or call the toll-free 1-800 phone number listed in the messaging and state that additional transitional refills are required.

1.5.14.1.1. **Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 forward will be: GRANDFATHER FILL MET MUST USE FORMULARY ALTERNATIVE CALL ###.###.####**

1.5.15. In the event the request is for a new member in the LTC setting, the additional transitional overrides will be authorized for the remaining portion of the 90 days left in the member’s transition period. The Customer Service Representative will then enter an override in the pharmacy claims adjudication system to allow the members to receive their additional transition fills to occur as described in the procedures section.

1.6. Smallest Available Package Size (SAPS)

1.6.1. Unbreakable/Smallest package size drug logic is configured to automatically allow a claim that is dispensed as the smallest package size available and whose day supply calculation based on prescribed directions exceed the day supply limitation set by the Sponsor.

1.6.2. Formulary lists are used to identify drugs whose smallest available package size is commonly dispensed for a certain days supply:

1.6.2.1. SAPSPKG365 – SAPS where the total package quantity is commonly less than or equal to the package size

1.6.2.2. SAPSTOTQTY365 – SAPS where the quantity submitted is commonly less than or equal to the total package quantity

1.6.2.3. The member's effective date on the enrollment file will be utilized to determine if they are within their first 90 days of initial enrollment with the Sponsor and qualify for a transition fill.

1.6.2.4. If the claim picks up a transitional script tag, it will be filtered through the Sponsor and bypass other UM edits (NF, PA, ST, and QL) to allow the claim to pay. These fills will count as their own transition fill and will be assigned a unique Misc. Handler (***TRANSD3PKGxx***).

1.6.2.5. UM edits are not overridden for SAPS outside of the transition period.

1.6.2.6. If the Sponsor allows for 30 and 90-day claims, day supply of 31-83 will pay during transition.

1.6.2.7. If the member is no longer within their Transition Period, claims for day supply of 31-83 will reject (88: DUR Reject Error). DUR override codes will be returned in the messaging to allow the Pharmacy to override the DUR reject at point of sale.

1.6.2.8. Drugs that require a B vs D determination will reject to allow Payer determination to occur before granting a member the SAPS Dispensing Limit and transition logic.

2. Implementation Statement Section 2: Pharmacy Notification, Description of Edits, and Process Pharmacies follow to resolve transition at Point of Sale

1. **Information is displayed as part of the pharmacy point of sale messaging after a claim has been submitted electronically by the pharmacy. Prompts for action and information are provided to the pharmacy.**
2. Any MISC Handler created for transitional purposes MUST have a naming convention that starts with **TRANSD3**. This handler will NOT drive Copays.
3. **The pharmacy is notified** when transition medication is processed at the point of sale via pharmacy messaging placed in the claims adjudication system.

3.1. For Paid Claims

3.1.1. Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 and forward for drugs subject to prior authorization will be: **PA REQUIRED, OR FOR ADDITIONAL LTC/TRANSITIONAL OVERRIDES CALL ###-###-####**

3.1.2. Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 and forward for drugs subject to step therapy will be: **MUST HAVE TRIED & FAILED DRUG _____ BEFORE DRUG _____. CALL ###-###-#### FOR ADDITIONAL LTC FILLS**

3.1.3. Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 and forward for drugs that are non-formulary will be: **TRANSITIONAL FILLS/DRUGS ONLY ALLOWED ## DAY SUPPLY.CALL ###-###-#### FOR ADDITIONAL TRANSITION or LTC TRANSITIONAL FILLS/DRUGS ONLY ALLOWED 31 DAY SUPPLY. CALL ###-###-#### FOR ADDITIONAL TRANSITION FILLS.**

3.2. For Rejected Claims

3.2.1. .Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 and forward for drugs subject to prior authorization will be: **PA REQUIRED. Call ###-###-#### or log on to https://envision.promptpa.com to initiate exception request.**

3.2.2. Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 and forward for drugs subject to step therapy will be: **MUST HAVE TRIED & FAILED _____ BEFORE _____. Call ###-###-#### or log on to https://envision.promptpa.com to initiate exception request.**

3.2.3. Actual pharmacy Messaging placed in the pharmacy claims adjudication system for 2016 and forward for drugs that are non-formulary will be: **NON-FORMULARY DRUG. TRANSITIONAL PERIOD OVER. USE FORMULARY PRODUCT. Call ###-###-#### or log on to https://envision.promptpa.com to initiate exception request.**

3. Implementation Statement Section 3: PBM Referential Information

3.1. PBM Implementation Statement: the PBM will maintain a detailed explanation related to transition configuration in the adjudication system in CS-SOP-T, Appendix A.

3.2. The PBM will maintain a detailed explanation related to how pharmacies are notified when a transition fill is processed at point of sale in CS-SOP-T, Appendix A

3.3. The PBM will maintain a detailed explanation of the process pharmacies follow to resolve transition medication edits at point of sale in CS-SOP-T, Appendix A.

4. Implementation Statement Section 4: Sponsor Oversight--PBM Monitoring and Identification of Issues

4.1. PBM shall offer testing of configuration and transition letter generation prior to the beginning of the new Sponsor year.

4.2. Monthly, the PBM will supply reporting to the Sponsor.

4.3. In the event an issue is identified, the PBM Account Manager will notify the Sponsor within 3 business days of discovery of the issue

Policies

1. Policy 1: Appropriate Transition Process

1.1. The Sponsor will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes enrollees whose current drug therapies may not be included in the Sponsor's formulary, it will effectuate a meaningful transition for:

(1) new enrollees into prescription drug Sponsors following the annual coordinated election period,

(2) newly eligible Medicare beneficiaries from other coverage,

(3) enrollees who switch from one Sponsor to another after the start of a contract year,

(4) current enrollees affected by negative formulary changes across contract years,

(5) enrollees residing in long-term care (LTC) facilities

(6) Level of Care Changes / Emergency Supplies

1.2. For (1) new enrollees into prescription drug Sponsors following the annual coordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one Sponsor to another after the start of a contract year.

1.2.1. The pharmacy claims adjudication system will be configured to automatically allow at least a month's supply (either one 30-day fill or multiple fills for up to a 30-day supply) of a non-formulary medication if the member is within the first 90 days of their eligibility with the Sponsor.

1.2.2. The member's effective date on the enrollment file will be utilized to determine if they are within their first 90 days of initial enrollment with the Sponsor..

1.2.3. Non-Formulary Drug claims will default to the Sponsor defined standard benefit, Tier 1. LIS members will not pay any more than their applicable LIS level copay. Non-LIS members will pay the same cost sharing for non-formulary drugs provided during the transition period as they would for non-formulary drugs approved through a formulary exception process.

1.2.4. Drugs requiring PA, ST, and QL overrides will be configured to automatically allow at least a month's supply (either one 30 day fill or multiple fills for up to a 30 day supply)

1.2.5. Drugs requiring PA, ST, and QL will pay at their appropriate copay Tier. LIS members will not pay any more than their applicable LIS level copay. Non-LIS members will pay the same cost share for transition fills of formulary drugs subject to utilization management edits as they would once the utilization management criteria are met.

1.2.6. Unbreakable/Smallest package size drugs will be configured to automatically allow a claim that is dispensed as the smallest package size available and whose day supply calculation based on prescribed directions exceed the day supply limitation set by the Sponsor.

1.3. Transition Across Sponsor Years: current enrollees affected by negative formulary changes across contract years (4)

1.3.1. For drugs that are removed from the formulary from Sponsor year to Sponsor year, or drugs that remain on the formulary but are subject to new prior authorization, step therapy, or quantity limits the upcoming Sponsor year.

1.3.1.1. Allow members who have been on one of these impacted drugs, and who are outside of the Sponsor's initial 90-day eligibility timeframe, to receive up to an accumulated 30-day supply (or 31 days if in the LTC setting) within the first 90-days of the benefit year. The pharmacy claims adjudication platform shall be configured by the PBM to allow this to occur without Point of Sale intervention.

1.3.1.2. To determine if a member is eligible for one of these transition fills, the Sponsor shall look 120 days from the new benefit year back in the enrollee's paid claim history for a paid claim. Since this has to do with Formulary changes from one year to the next, we assume the member was with the Sponsor the previous benefit year.

1.3.1.3. If a paid claim is present within the look back timeframe, the transition fill will automatically process.

1.3.1.3.1. For drugs that are non-formulary in the new Sponsor Year, the claim will default to the Sponsor defined standard benefit, Tier 1. LIS members will not pay any more than their applicable LIS level copay.

1.3.1.3.2. Drugs requiring ST, PA, or QL will pay at their appropriate copay Tier for Non-LIS members. LIS members will not pay any more than their applicable LIS level copay.

1.4. For Enrollees that are LTC residents (5)

1.4.1. The pharmacy claims adjudication system will be configured to allow a one time temporary fill of at least a month's supply, dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed, of a non-formulary medication, or a medication that requires prior authorization, step therapy, or quantity limits to process automatically when submitted by a LTC pharmacy within the Sponsor's pharmacy network if the member is within the first 90 days of their eligibility. Transition fills of at least a month's supply, dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed, will be allowed for the member during the entire 90 days of their initial eligibility with the Sponsor.

1.4.2. The member's effective date on the enrollment file will be utilized to determine if they are within their first 90 days of initial enrollment with the Sponsor.

1.4.3. The pharmacy must submit the claim for up to a 31 day supply of medication and must submit the number 3,4 or 9 in the patient residence field of the claim for the claim for non-formulary medications (including those medications with ST/PA/QL edits) to automatically process.

1.4.4. If the pharmacy does not submit a 3, 4 or 9 in the patient location field of the claim, and the claim is for a 31-day supply, the claim will reject and the pharmacy will receive a message that only a 30 day supply of the medication is allowed for a transitional fill.

1.4.5. For Non-LIS members, the paid claim will default to the Sponsor defined standard benefit, Tier 1 for non-formulary medications and drugs requiring PA, ST, or QL, will pay at their appropriate copay Tier. LIS members will not pay any more than their applicable LIS level copay.

1.4.6. Current LTC enrollees impacted by a formulary change across Sponsor years, follow the guidance above for this population. Patient residence field requirements apply.

1.5. Level of Care Changes / Emergency Supplies:

1.5.1. If a current member experiences a level of care change, is a hospice patient who is receiving a Part D drug that is not eligible for hospice coverage, enters the LTC setting from another care setting, or is in LTC and requires an emergency fill of a non-formulary drug, including those medications on the formulary subject to PA, ST, or QL, or requires an extension of their transition period for any other reason (i.e. the

member is either outside of their transition period or previously has received the transition fill)

1.5.2. Pharmacies may submit certain Submission Clarification Codes (SCC) indicating a level of care change or the need for an emergency override. Upon submission of appropriate the SCC and identification of the LTC setting, applicable claims will adjudicate accordingly.

1.5.3. If a SCC is not submitted, the PBM will message to pharmacies to call for a transition override for all claims rejected for non-formulary status or requiring a PA, ST, or QL.

1.5.4. When a member/pharmacy calls the Sponsor, these inquiries will be handled and approved on a case-by-case basis by the PBM's Clinical Pharmacy staff.

1.5.5. Once the Clinical staff approves a transition fill for one of these circumstances (NFE, ST, PA, or QL)

1.5.6. The member's effective date on the enrollment file will be utilized to verify that they fall outside of their first 90 days of initial enrollment with the Sponsor.

1.5.7. The Sponsor's Customer Service Representative will place an override in the adjudication system to allow the claim to pay without completing the NFE, PA, ST, or QL

1.5.8. The member prior auth screen in the adjudication system will be set up as a "trans d <insert tier of drug>" on tab 2 (Action tab) in the "mark script as" field of the prior authorization screen to indicate that this a ST/PA/QL transition override

1.5.9. The override will be set up to expire no later than 72 hours from the time it was entered.

1.5.10. The override will only allow a 30/31 day supply of the medication (30 days for the outpatient setting and 31 days for the LTC setting).

1.5.11. For Non LIS members, drugs requiring PA, ST, or QL, will pay at their appropriate copay Tier. NFE will pay at the Sponsor defined standard Tier 1. LIS members will not pay any more than their applicable LIS level copay.

1.5.12. The PBM's Customer Service Representative will then initiate the coverage determination process.

1.5.12.1. All manual override claims will be reviewed daily by a Clinical Coordinator to ensure the override was configured properly and the member was charged the appropriate copay.

1.5.12.2. Any overrides identified as being incorrect will be provided to an Envision Help Desk Supervisor for correction and adjudication within 24 hours of receipt of notice.

1.6. Determination of a New Prescription

1.6.1. If the member is within the first 90 days of their initial eligibility with the Sponsor and the Sponsor cannot determine if a prescription is a new prescription, they will be instructed to follow the processes set forth above.

2. Policy 2: Submission of transition policy to CMS

2.1. The Sponsor will submit a copy of its transition policy to CMS annually during the first formulary submission window for the upcoming Sponsor year and as requested by CMS.

3. Policy 3: Non-formulary Drugs, medical review, and witching to alternatives failing determination

3.1. Transition process requirements apply to non-formulary drugs, meaning both

3.1.1. (1) Part D drugs that are not on the Sponsor's formulary, and

3.1.2. (2) Part D Drugs that are on the Sponsor's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a Sponsor's utilization management rules.

3.2. Details of the Sponsor's medical review of non-formulary drug requests are in the Sponsor's Coverage Determination Policy and Procedure.

3.3. The Process for switching new Part D Sponsor enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination are in the denial notice provided to the Member.

4. Policy 4: System Capabilities for Temporary Supply of Non-formulary Part D drugs

4.1. The Sponsor has systems capabilities that provides a temporary supply of non-formulary Part D drugs to accommodate the immediate needs of an enrollee, as well as to allow the Sponsor and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication *or* the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

4.2. Adjudication details are in the implementation process above.

5. Policy 5: Retail one month's supply

5.1. In the retail setting, the Sponsor will provide at least a one-time, temporary fill of at least a month's supply of medication (unless the enrollee presents a prescription written for less than a month's supply, in which case the Sponsor will allow multiple fills to provide up to a total of a month's supply of medication) anytime within the first 90 days of the beneficiary's

enrollment in a Sponsor, beginning on the enrollee's effective date of coverage with the Sponsor.

5.2. If the smallest available package size exceeds a 30-day supply, a transition supply for an appropriate days supply exceeding 30 will be provided.

6. Policy 6: Cost Share Considerations

6.1. Cost sharing for transition supplies for low-income subsidy (LIS) eligible enrollees will never exceed the statutory maximum copayment amounts.

6.2. For non-LIS enrollees, the Sponsor will charge the same cost sharing for non-formulary Part D drugs provided during the transition that would apply for non-formulary drugs approved through a formulary exception in accordance with § 423.578(b) and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply if the utilization management criteria are met.

7. Policy 7: Long-term care setting

7.1. In a long-term care setting, the transition policy provides for a one time temporary fill of at least a month's supply (unless the enrollee presents with a prescription written for less) which should be dispensed incrementally as applicable under 42 CFR §423.154 and with multiple fills provided if needed during the first 90 days of a beneficiary's enrollment in a Sponsor, beginning on the enrollee's effective date of coverage. (1)

7.2. After the transition period has expired, the transition policy provides for a 31-day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) while an exception or prior authorization is requested and (2)

7.3. For enrollees being admitted to or discharged from a LTC facility, early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge. (3)

7.4. If the smallest available package size exceeds the month's supply, a transition supply for an appropriate days supply will be provided.

7.5. Policy 1 contains details on LTC processes

8. Policy 8: Utilization Management Edits during transition

8.1. The pharmacy claims adjudication system will be configured to apply the following edits to occur during transition at point-of-sale

8.1.1. Edits to help determine Part A or B versus Part D coverage and Hospice vs. Part D coverage

8.1.2. Edits to prevent coverage of non-part D drugs (i.e. excluded drugs)

8.1.3. Edits to promote safe utilization of a Part D drug (i.e. quantity limits based on FDA maximum recommended daily dose, early refill edits)

8.1.4. The Sponsor will ensure that pharmacies can resolve step therapy and prior authorization during transition at point-of-sale.

9. Policy 9: Refills for transition prescriptions

9.1. The Sponsor provides refills for transition prescriptions dispensed for less than the written amount due to quantity limit safety edits or drug utilization edits that are based on approved product labeling.

9.2. The Sponsor's Customer Service Representatives will place an override in the pharmacy claims adjudication system in the MPA screen to allow the claim to pay for additional refills.

9.2.1. The MPA will be set up to allow the remainder of refills to process by completing the date range on tab 1 of the MPA screen. The date range should be configured for the remainder of the 30 (retail)/31(LTC) days supply based on how many days the allowable fill is for.

9.2.2. The MPA will be set up as a "Trans-D<insert tier of drug>" on tab 2 (Action tab) in the "Mark Script As" field of the MPA screen to indicate this transition override.

10. Policy 10: Brand-new prescriptions distinction

10.1. The Sponsor applies the transition processes to a brand-new prescription for a non-formulary Part D drug if it cannot make the distinction between a brand-new prescription for a non-formulary drug and an ongoing prescription for a Part D non-formulary drug at point of sale. In other words, a brand-new prescription for a non-formulary drug will not be treated any differently than an ongoing prescription for a non-formulary drug when a distinction cannot be made at the point of sale.

11. Policy 11: Written Notices with the CMS transition requirements

11.1. The Sponsor sends written notice via U.S. first class mail to enrollee within three business days of adjudication of a temporary transition fill.

11.2. The notice includes (1) explanation of the temporary nature of the transition supply an enrollee has received (2) instructions for working with the Sponsor and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the Sponsor's formulary (3) an explanation of the enrollee's right to request a formulary exception and (4) a description of the procedures for requesting a formulary exception.

11.3. For long- term care residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less, consistent with the requirements under 42

CFR 423.154(a)(1)(i), the written notice must be provided within 3 business days after adjudication of the first temporary fill.

11.4. The Sponsor uses the CMS model Transition Notice via the file-and-use process and makes reasonable efforts to notify prescribers of affected enrollees who receive a transition notice.

12. Policy 12: Prior Authorization or Exception forms

12.1. The Sponsor makes available prior authorization or exceptions request forms upon request to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on Sponsor web sites.

13. Policy 13: Transition across contract years

13.1. The Sponsor extends its transition policy across contract years should a beneficiary enroll in a Sponsor with an effective enrollment date of either November 1 or December 1 and need access to a transition supply.

13.2. The Sponsor will send enrollees with a November 1 or December 1 effective enrollment date and ANOC as soon as practical after the effective enrollment date to serve as advance notice of any formulary or benefit changes in the following contract year.

14. Policy 14: Transition policy link from Medicare Prescription Drug Sponsor Finder

14.1. The Sponsor makes their transition policy available to enrollees via a link from the Medicare Prescription Drug Sponsor Finder to their Sponsor website and including it in pre-and post-enrollment marketing materials as directed by CMS.

15. Policy 15: Extension of transition period

15.1. The Sponsor will make arrangements to continue to provide necessary Part D drugs to enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).

15.2. Transition Fills for Coverage Exceptions

15.2.1. The Sponsor will allow a transition fill for enrollees who request an exception but the Sponsor has failed to issue a timely decision on the request by the end of the transition period by performing the following;

15.2.2. The member's effective date on the enrollment file will be utilized to verify that they fall outside of their first 90 days of initial enrollment with the Sponsor.

15.2.3. The enrollee's claims history will be reviewed to determine that a previous transition fill has been issued.

15.2.4. The Sponsor's clinical staff will be contacted to verify that a Coverage Determination decision is in the process of being effectuated.

15.2.5. PA, ST, or QL, overrides will be configured at Point of Sale

15.2.6. The Sponsor's Customer Service Representative will place an override in the system to allow the claim to pay without completing the PA or ST requirements.

15.2.7. The member prior auth screen in the adjudication system will be set up as a "trans d <insert tier of drug>" on tab 2 (Action tab) in the "mark script as" field of the prior authorization screen to indicate that this a PA, ST, or QL, transition override.

15.2.8. The override will be set up to expire no later than 72 hours from the time it was entered. The override will only allow a 30/31 day supply of the medication (30 days in the retail setting and 31 days in the LTC setting).

15.2.9. Drugs requiring PA, ST, or QL, will pay at their appropriate copay Tier for Non-LIS members. LIS members will not pay any more than their applicable Drugs requiring PA, ST, or QL, will pay at their appropriate copay

15.2.10. Tier for Non-LIS members. LIS members will not pay any more than their applicable

15.2.11. Non-Formulary claims will be configured to be overridden at Point of Sale

15.2.12. The Sponsor's Customer Service Representative will place an override in the system to allow the claim to pay for the non- formulary drug.

15.2.12.1. The PA will be set up as a "trans d <insert tier of non-preferred drug>" on tab 2 (Action tab) in the "mark script as" field of the prior authorization screen to indicate that this a non-formulary transition override.

15.2.12.2. The override will be set up to expire no later than 72 hours from the time it was entered.

15.2.12.3. The override will only allow a 30-day supply of the medication or 31-day supply if the member is in an LTC setting.

15.2.12.4. The claim will default to the Sponsor defined standard benefit, Tier 1 for Non-LIS members. LIS members will not pay any more than their applicable LIS level copay.

15.2.13. All manual override claims will be reviewed on a daily basis by a Clinical Coordinator to ensure the override was configured properly and the member was charged the appropriate copay.

15.2.14. Any overrides identified as being incorrect will be provided to the PBM Help Desk Supervisor for correction and adjudication within 24 hours of receipt of notice.

16. Policy 16: Negative Formulary changes in the upcoming year

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

16.1.1. (1) providing a transition process at the start of the new contract year, details are in the implementation statement and Policy 1 OR

16.1.2. (2) effectuating a transition prior to the start of the new contract year.