Policy Title:	Part D Formulary Transition Policy				
Policy Number:	PHARM-001	**Version Number:**	4.0	**Effective Date:**	01/01/2025
Reviewed Date:	08/16/2024	**Revision Date:**	09/30/2024	**Approval Date:**	10/11/2023
Citation/Guidance Reference:					
Business Owner Details	**Name:**	Alfred Romay, Pharm.D.			
	Signature:	*Alfred Romay, Pharm.D.*			
	Title:	Vice President, Pharmacy Operations			

PURPOSE:

Solis Health Plans shall implement a formulary transition procedure in accordance with Medicare guidance. A transition process will be maintained for enrollees whose current drug therapies may not be included in Solis Health Plan's formulary, and will effectuate a meaningful transition for the following instances:

1. The transition of new enrollees into prescription drug plans following the annual coordinated election period
2. The transition of newly eligible Medicare beneficiaries from other coverage
3. Enrollees who switch from one plan to another after the start of the contract year
4. Current enrollees affected by negative formulary changes across contract years
5. Enrollees residing in LTC facilities
6. Expediting transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care

DEFINITION(S):

Annual Notice of Change (ANOC): Notification to advise enrollees of changes to their benefit.
Long-term Care (LTC): A variety of services which help meet both the medical and non-medical needs of people with a chronic illness or disability who cannot care for themselves for long periods of time.
Pharmacy Benefit Manager (PBM): an entity that provides pharmacy benefit management services for a Part D sponsor.
Prior Authorization (PA): Pre-approval which needs to be obtained for the prescription to be covered by the plan.
Step Therapy (ST): Process through which other formulary medications must be tried and failed to obtain coverage of the desired medication

POLICY:

A. Solis Health Plans PBM vendor's adjudication system logic automatically identifies claims eligible for a temporary supply of non-formulary Part D drugs (including Part D drugs that are on the Part D formulary, but require prior authorization, step therapy or that have an approved QL lower than the beneficiary's current dose under our utilization management rules) and effectuates payment to accommodate the immediate needs of the enrollee.

B. For these transitional claims, a transition notice will be sent to both the enrollee and the prescriber. This notification allows the enrollee sufficient time to collaborate 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. This will promote continuity of care and avoid interruptions in drug therapy.

C. In certain circumstances, Solis Health Plans in collaboration with the PBM will extend the transition period and provide the necessary drugs if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

D. Solis Health Plans will ensure enrollees in their transition period are provided temporary fills for non-formulary drugs (including Part D drugs that are on the formulary but require prior authorization, require step therapy, or that have an approved QL lower than the beneficiary's current dose) during the first 90 days of their benefit period. In certain instances, drug utilization management edits will be applied during the beneficiary's transition period. These edits are limited to:

- Edits to help determine Part A or B vs. Part D coverage
- Edits to prevent coverage of non-Part D drugs (i.e., excluded drugs or formulary drugs being dispensed for an indication that is not medically accepted)
- Utilization Review Edits to promote safe utilization of a Part D drug (i.e., enrollees-level opioid claim edits, quantity limits based on FDA maximum recommended daily dose, early refill edits)

PROCEDURE:

1. Enrollees and situations affected by the transitional fill policy in which Solis Health Plans will apply a transition process consistent with 42 CFR §423.120(b)(3):

- The transition of new enrollees into prescription drug plans following the annual coordinated election period
- The transition of newly eligible Medicare beneficiaries from other coverage
- Enrollees who switch from one plan to another after the start of the contract year
- Current enrollees affected by negative formulary changes across contract years
- Enrollees residing in LTC facilities
- Expediting transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.

2. General Guidelines

A. Solis Health Plans transition process is applicable to:

1) Part D drugs that are not on Solis Health Plans Part D formulary

2) Part D drugs that are on Solis Health Plans Part D formulary but require prior authorization, exceed quantity limits or require step therapy under Solis Health Plans utilization management rules.

B. Solis Health Plans ensures that we provide our enrollees, who have used a transition benefit, with the appropriate assistance and information necessary to enable them to better understand the purpose of the transition supply. This includes:

1) Analyze claims data to determine which enrollees require information about their transition supply.

2) Contacting those enrollees to ensure they have the necessary information to enable them to switch to a formulary product or, as an alternative, to pursue necessary prior authorizations or formulary exceptions.

a. Exception requests are processed consistent with CMS requirements outlined in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for medical review of nonformulary drug requests and to determine whether to approve or deny the request based on the exception criteria established.

b. Should an exception request be denied, the enrollee and prescriber receive a notice that provides information regarding appeal rights and the denial decision, including any specific formulary criteria and/or therapeutically appropriate formulary alternatives that must be satisfied for approval. A enrollees may switch to these therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

3) Solis Health Plans will be able to handle and respond to enrollee questions regarding the transition process

4) On a case-by-case basis, Solis will continue to make any arrangements necessary to ensure we are providing necessary drugs to an enrollee by extending the transition period if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

3. Solis Health Plans transition processes will apply to all new prescriptions for a non-formulary drug. If we are unable to make a distinction between a new prescription and an ongoing prescription for a non-formulary drug at the point-of-sale, we will provide the enrollee with a transition fill.

4. Timeframes for Transitional Fills

A. Temporary Fills

1) Within the first 90 days of coverage for a new enrollee under a Part D plan, the plans PBM will provide a temporary fill when our new enrollees request a refill of a nonformulary drug, including Part D drugs that are on Part D formulary but require prior authorization, exceed quantity limits, or require step therapy under this medication utilization management policy.
2) This 90- day timeframe applies to retail, home infusion, long term care and mail order pharmacies.

3) Since certain enrollees may join a plan at any time during the year, this requirement will apply beginning on an enrollees' first effective date of coverage, and not only to the first 90 days of the contract year.
4) If an enrollee leaves a plan and re-enrolls during the original 90-day transition period, the transition period begins again with the new effective date of enrollment. However, if there is no gap in coverage, there is no new transition period.
5) The 90 -day timeframe assists those beneficiaries transitioning from other prescription drug coverage who obtained extended (i.e., 90-day) supplies of maintenance drugs prior to the last effective date of their previous coverage.

B. Outpatient Setting (Retail Pharmacies)

The temporary supply of non-formulary Part D drugs, including Part D drugs that require prior authorization, exceed quantity limits, or require step therapy under Solis Health Plan utilization management policy, must be for at least a month's supply of medication.

1) If the enrollee presents with a prescription written for less than a month's supply, the plans PBM will allow multiple fills to provide at least a month's supply of medication.
2) Allow for multiple fills for unbreakable packages that will allow at least a 1 month's supply to be dispensed during a beneficiary's transition.

C. Long-Term Care (LTC) Setting – The temporary supply of non-formulary Part D drugs, including Part D drugs that require prior authorization, exceed quantity limits, or require step therapy under Solis Health Plans utilization management policy, for a new enrollee in a LTC facility for at least a 1 months' supply of medication consistent with the dispensing increments (unless the prescription is written for less), with refills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.

1) Solis Health Plans will not use early refill edits to limit enrollees being admitted to or discharged from a LTC facility from appropriate and necessary access to their Part D benefit and such enrollees are allowed access to a refill upon admission or discharge.

2) Refer to: Emergency Supply for Current Enrollee regarding LTC Emergency Supply

D. Transition Extension:

1) Solis Health Plans will continue to provide necessary drugs to an enrollee via an extension of the transition period. If the decision is made to allow an extension by a Solis Health Plans or the plans PBM, an override will be entered in the PBM system.

2) This extension is granted on a case-by-case basis considering whether the enrollees' exception request or appeal has not been processed by the end of the minimum transition period.

3) Solis Health Plans and or the plans PBM provides clear guidance to the affected enrollees in the transition notice sent to enrollees, explaining how to proceed after a temporary fill is provided, so that an appropriate and meaningful transition can be effectuated by the end of the transition period.

4) Solis Health Plans and the plans PBM recognizes that until the transition is made, either through a switch to an appropriate formulary drug or a decision is made regarding an exception request, continuation of drug coverage is necessary (other than for drugs not covered under Part D).

5. Transition Across Contract Years

A. After enrollee receive their ANOC by late September of a given year, Solis Health Plans will select at least one of the following two options for effectuating an appropriate and meaningful transition for enrollee whose drugs are affected by negative formulary changes from one contract year to the next:

1) Provide a transition process for current enrollees at the start of the new contract year. To prevent coverage gaps, should this option be selected, the plans PBM will provide a temporary supply of the requested prescription drug and provide our affected enrollees with the required transition notice, OR
2) Effectuate a transition for current enrollees prior to the start of the new contract year. If this option is selected, the PBM will work to:

   a. Prospectively transition current enrollees to a therapeutically equivalent formulary alternative; and

   b. Complete any requests for exceptions to the new formulary prior to the start of the contract year.

      I. If the PBM or Solis Health Plans approves an exception request, they will authorize payment prior to January 1st of the new contract year

      II. If, however, if Solis Health Plans or the plans PBM has not successfully transitioned affected enrollees to a therapeutically equivalent formulary alternative or processed an exception request by January 1st, we will provide a transition supply (and the required transition notice) beginning January 1st and until such time as it has effectuated a meaningful transition.

B. Current Enrollees: Where the plans PBM can identify objective information demonstrating that a meaningful transition has occurred or the enrollee lacks documented ongoing therapy, access to a transition supply in the new contract year for this enrollee is not required.

Objective information includes:

1) Processing an exception request
2) Evidence of a new prescription claim for a formulary alternative processed prior to the start of the contract year
3) Greater than 108 days of eligibility with no claims history in the last 180 days from the prescription date of service

However, if the PBM is unable to identify such objective evidence, the PBM will provide a transition supply in the new contract year and provide the required transition notice.

C. New Enrollees: Solis Health Plans and the plans PBM also extends the transition policy across contract years where an enrollee enrolls into one of our plans with an effective enrollment date of either November 1st or December 1st and that enrollee needs access to a transition supply.

1) In addition, Solis Health Plans will send these enrollees, with a November 1st or December 1st effective enrollment date, an ANOC as soon as practicable after the effective enrollment date.

2) The ANOC will still serve as advance notice of any formulary or benefit changes in the following contract year.

6. Emergency Supply for Current Enrollees

a. Solis Health Plans transition policy covers emergency supplies of non-formulary Part D drugs for LTC facility residents.

b. During the first 90 days after an enrollee's enrollment, he/she will receive a transition supply. However, to the extent that a enrollees in an LTC setting is outside his/her 90-day transition period, Solis Health Plans or the plans PBM will provide an emergency supply of non-formulary Part D drugs, including Part D drugs that are on Solis Health Plans Part D formulary that would otherwise require prior authorization, exceed quantity limits, or require step therapy under utilization management policy, while an exception or prior authorization is requested.

c. These emergency supplies of non-formulary Part D drugs will be for at least 31 days of medication, regardless of dispensing increments, unless a prescriber writes the prescription for less than 31 days.

d. In cases where the smallest available marketed package size is not available for less than a 31-day supply, the plans PBM will still provide an emergency supply when required.

7. Level of Care Changes

a. Solis Health Plans transition process provides for other circumstances that exist in which unplanned transitions for current enrollees could arise and in which prescribed drug regimens may not be on our formulary. These circumstances usually involve the level of care changes for an enrollee that is changing from one treatment setting to another, such as:

1) Enrollees who enter LTC facilities from hospitals with a discharge list of medications from the hospital formulary with very short-term planning considered (i.e., under 8 hours)

2) Enrollees who are discharged from a hospital to a home with very short-term planning considered

3) Enrollees who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary

4) Enrollees who give up hospice status to revert to standard Medicare Part A and B benefits

5) Enrollees who end an LTC facility stay and return to the community

6) Enrollees who are discharged from psychiatric hospitals with drug regimens that are highly individualized

b. The foregoing circumstances often result in enrollees and/or providers utilizing Solis Health Plans or the plans PBM exceptions and/or appeals processes. For these unplanned transitions, Solis Health Plans or the plans PBM make coverage determinations and re-determinations as expeditiously as the enrollee's health condition requires.

c. Solis Health Plans transition process ensures appropriate medication reconciliation for enrollee upon discharge from LTC facilities or other facilities, so that an effective transition of care can be accomplished.

1) The current standard of care promotes caregivers receiving outpatient Part D prescriptions in advance of discharge from a Part A stay. Members, through no fault of their own, may not have access to the remainder of the previously dispensed prescription.
2) Solis Health Plans process allows the member to access a refill upon admission to, or discharge from, a LTC facility

e. The PBM uses claims data to determine if the member has experienced a level of care change and allows a transition fill where applicable. When claims data cannot be used to determine a level of care change, a pharmacy may need to call the PBM Pharmacy Help Desk to process a point-of-sale override to effectuate this type of transition fill.

8. Edits for Transitional Fills

a. Solis Health Plans transition process ensures that a new member is able to leave a network pharmacy with a temporary supply of non-formulary Part D drugs without unnecessary delays.
b. The PBM applies certain drug utilization management edits during a member's transition period. Drug utilization management edits that are appropriate during a member's transition period include the following:

1) Edits to help determine Part A or B versus Part D coverage

2) Edits to prevent coverage of non-Part D drugs (i.e., excluded drugs or formulary drugs being dispensed for an indication that is not medically accepted)

3) Utilization Review Edits to promote safe utilization of a Part D Drug (i.e., member level opioid claim edit, quantity limits based on FDA maximum recommended daily dose, early refill edits)

c. While the Solis Health Plans may implement step therapy, prior authorization or quantity limits edits during transition, this is only applied to edits that can be resolved at the point of sale.

1) The PBMs adjudication system is set up so that all non-formulary Part D drugs and all drugs requiring utilization management edits will process automatically for a member in their transition period. Our adjudication processing system, for a claim for a beneficiary in their transition period, will bypass all edits except those described in Section 8b.
2) During transition, Solis Health Plans or the plans PBM allows overrides to these edits if the prescriber will not authorize the change at point of sale. 3) If the edit is overridden only for transition purposes, the member will be notified so that he/she can begin the exception process, if necessary.

d. Solis Health Plans may implement quantity limits that are based on approved product labeling during a member's transition period. Solis Health Plans will provide 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 to meet the transition supply requirement. Irrespective of transition, all edits are subject to exceptions and appeals.

1) Solis Health Plans transition process ensures that affected members are made aware of quantity limits and the fact that an exception is required to obtain a greater quantity.

2) Solis Health Plans and or the plans PBM expeditiously processes all exception requests so that members will not experience unintended interruptions in medically-necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

3) Enrollee-level opioid point-of-sale claim edits (and cumulative opioid MED edits) may be applied during transition.

e. To meet CMS' intent for messaging to pharmacies for transition fill notices at point of sale, in accordance with Chapter 6 Sec. 30.4.10 and Chapter 14 Sec. 50.5, The PBM has implemented enhanced transition fill messaging functionality in the claims adjudication system. This provides messaging to the submitting pharmacy with notification of a transition fill for the enrollee.

9. Cost-Sharing Considerations

a. Solis Health Plans will charge cost-sharing for a temporary supply of drugs provided under our transition process.

b. Cost-sharing for transition supplies for low-income subsidy (LIS) eligible enrollees can never exceed the statutory maximum co-payment amounts.

c. For non-LIS eligible enrollees:

1) The PBM or Solis Health Plans charges cost-sharing for a temporary supply of drugs provided under its transition process based on one of our approved drug cost sharing tiers (if the sponsor has a tiered benefit design). This cost-sharing is consistent with cost-sharing that Solis Health Plans would charge for non-formulary drugs approved under a coverage exception.

2) The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

10. Transition Notices

a. The plans PBM sends written notice consistent with CMS transition requirements to members within three business days after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on Part D formulary but require prior authorization, exceed quantity limits, or require step therapy under utilization management policy). If the enrollee completes the transition supply in several fills, the plans PBM will send the notice with the first fill only. All transition notices include:

1) An explanation of the temporary nature of the transition supply the member or new enrollee has received

2) Instructions for working with Solis Health Plans and the prescribing clinician to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the respective Part D formulary

3) An explanation of the member's right to request a formulary exception including processing timeframes and the member's right to request an appeal if the exception decision is unfavorable

4) A description of the procedure for requesting a formulary exception

5) 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 three (3) business days after adjudication of the first temporary fill.

a. The appropriate transition letter, based on the reason for the initial denial of the medication, is sent via U.S. First Class mail to each member, who receives a transition fill.

1) The plans PBM will use the CMS model Transition Notice.
2) Solis Health Plans makes prior authorization and exception request forms available (upon request via mail, fax, or email, and are available on Solis Health Plans web site to both members and prescribing physicians.

b. The plans PBM provides the prescriber of record with a copy of the transition notice that was sent to the member labeled "PRESCRIBER COPY" via U.S. first class mail or fax.

c. Solis Health Plans make general information about the transition processes available to members on the web site. Plan sponsors also include transition process information in pre- and post-enrollment marketing materials as directed by CMS.

ATTACHMENTS: None

Revision Record			
Revision Date	Version Number	Revised By	Revision description
08/16/2018	1.0	Laurie George	Creation of new policy
08/15/2019	2.0	Milagros Yzquierdo	Review
06/15/2023	3.0	Alfred Romay	Review
10/11/2023	4.0	Alfred Romay	Review
09/30/2024	5.0	Alfred Romay	Review