Signature Advantage, LLC (H2400) CY2025 Medicare Part D Transition Policy

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Policy Purpose:

The purpose of this policy is to describe Signature Advantage's process for transition (as adopted from and administered by its PBM, Elixir/MedImpact "MedImpact") 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), MedImpact. 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 MedImpact for delegated activities.

All references to the “Sponsor” refer to Signature Advantage, LLC.

All references to PBM refer to MedImpact.

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.

1.1 Overview

The Plan’s PBM supports in administering a transition process that is in compliance with the established CMS transition requirements.

This policy is necessary with respect to:

(1) New enrollees into prescription drug plans following the annual coordinated election period;

(2) Newly eligible Medicare beneficiaries from other coverage;

(3) Enrollees who switch from one plan to another after the start of a contract year;

(4) Current enrollees affected by negative formulary changes across contract years; and

(5) Enrollees residing in long-term care (LTC) facilities.

The Plan’s PBM will ensure that its transition policy will apply to non-formulary drugs, meaning both (1) Part D drugs that are not on a plan’s formulary, and (2) Part D drugs that are on a plan’s formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary’s current dose, under a plan’s utilization management rules. The Plan’s PBM will ensure that its policy addresses procedures for medical review of non-formulary drug requests, and when appropriate, a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Also in accordance with CMS requirements, the Plan’s PBM ensures that drugs excluded from Part D coverage due to Medicare statute are not eligible to be filled through the transition process.
However, to the extent that a Plan covers certain excluded drugs under an Enhanced benefit, those drugs should be treated the same as Part D drugs for the purposes of the transition process.

1.2 Transition Population

The Plan's PBM will maintain an appropriate transition process consistent with 42 CFR §423.120(b)(3) that includes a written description of how, for enrollees whose current drug therapies may not be included in their new Part D plan's formulary, it will effectuate a meaningful transition for: (1) new enrollees into prescription drug plans following the annual coordinated election period, (2) newly eligible Medicare beneficiaries from other coverage, (3) enrollees who switch from one plan 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.

1.3 Transition Period

The Plan's PBM allows Plans to choose the number of transition days offered under their transition policy. CMS requires a minimum of 90 days from the start of coverage under a new plan. The 90 days are calculated from the plan start date. The Plan's 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. Plans may choose to enhance their transition policy to provide coverage beyond the CMS minimum requirements.

The Plan's PBM will ensure that it will apply all 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 the point-of-sale.

1.4 Implementation Statement

a) **Claims Adjudication System:** The Plan's PBM has systems capabilities that allow the Plan's PBM to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan 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.

b) **Pharmacy Notification at Point-Of-Sale:** The Plan's PBM utilizes the current NCPDP Telecommunication Standard to provide POS messaging. Pharmacy messages are modified based on industry standards.

c) **Edits During Transition:** The Plan's PBM will only apply the following utilization management edits during transition at point-of-sale: 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 must be resolved at point-of-sale.

The Plan's PBM will ensure that the transition policy 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.

As outlined in 42 CFR §423.153(b), The Plan's PBM has implemented Point-of-Sale (POS) PA edits to determine whether a drug is covered under Medicare Parts A or B as prescribed and administered, is being used for a Part D medically accepted indication or is a drug or drug class or its medical use that is excluded from coverage or otherwise restricted under Part D (Transmucosal Immediate Release Fentanyl (TIRF) and Cialis drugs as an example).

d) **Pharmacy Overrides at Point-Of-Sale:** During the member's transition period, all edits (with the exception of those outlined in section 1.4(c)) associated with non-formulary drugs are automatically overridden at the point-of-sale. Pharmacies can also contact the Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides. The Plan's PBM can also accommodate overrides at point-of-sale for emergency fills as described in section 1.7.

Please see section 1.10 for specific information for the processing of non-formulary drugs in the Six Classes of Clinical Concern.

1.5 Transition Fills for New Members in the Outpatient (Retail) Setting

The Plan's PBM will ensure that in the retail setting, the transition policy provides for a one time temporary fill of at least a month's supply of medication (unless the enrollee presents with a prescription written for less than a month's supply in which case the Part D Sponsor must allow multiple fills to provide up to a total of a month's supply of medication) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage. If a brand medication is being filled under transition, the previous claim must also be brand (based on Comprehensive NDC SPL Data Elements File [NSDE] marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).

1.6 Transition Fills for New Members in the LTC Setting

The Plan's PBM will ensure that in the long-term care setting: (1) 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 plan, beginning on the enrollee's effective date of coverage (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 (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.

1.7 Emergency Supplies and Level of Care Changes for Current Members

An Emergency Supply is defined by CMS as a one-time fill of a non-formulary drug that is necessary with respect to current members in the LTC setting. Current members that are in need of a one-time Emergency Fill or that are prescribed a non-formulary drug as a result of a level of care change can be placed in transition via an NCPDP pharmacy submission clarification code. The Plan's PBM can also accommodate a one-time fill in these scenarios via a manual override at point- of-sale.

Upon receiving an LTC claim transaction where the pharmacy submitted a Submission Clarification Code (SCC) value of "18", which indicates that the claim transaction is for a new dispensing of medication due to the patient's admission or readmission into an LTC facility, The Plan's PBM claims adjudication system will recognize the current member as being eligible to receive transition supplies and will only apply the point-of-sale edits described in section 1.4(c) of this policy. In this instance, the Plan does not need to enter a point-of-sale override.

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: (1) providing a transition process at the start of the new contract year or (2) effectuating a transition prior to the start of the new contract year.

POS logic is able to accommodate option 1 by allowing current members to access transition supplies at the point-of-sale when their claims history from the previous calendar year contains an approved claim for the same drug that the member is attempting to fill through transition and the drug is considered a negative change from one plan year to the next. To accomplish this, POS looks for Part D claims in the member's claim history that were approved prior to January 1 of the new plan year, and that have the same HICL value as the transition claim. Additionally, if a brand medication is being filled under transition, the previous claim must also be brand (based on NSDE marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status).

Negative changes are changes to a formulary that result in a potential reduction in benefit to members. These changes can be associated to removing the covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management. The transition across contract year process is applicable to all drugs associated to mid-year and across plan-year negative changes.

1.8 Transition Extension

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). On a case-by-case basis, point-of-sale overrides can also be entered by the Plan or by The Plan's PBM (if authorized by the Plan to do so) in order to provide continued coverage of the transition drug(s).

1.9 Cost-sharing for Transition Supplies

The Plan's PBM will ensure that cost-sharing for a temporary supply of drugs provided under its transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS enrollees, a sponsor must 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 42 CFR §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.

1.10 Six Classes of Clinical Concern

Per CMS guidance, members transitioning to a plan while taking a drug within the six classes of clinical concern must be granted continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in the plan as long as the drug remains on formulary. Utilization management restrictions (PA and/or Step Therapy), which may apply to new members naïve to therapy, are not applied to those members transitioning to the Medicare Part D plan on agents within these key categories. The six classes include:

1) Antidepressant;
2) Antipsychotic;
3) Anticonvulsant;
4) Antineoplastic;
5) Antiretroviral; and
6) Immunosuppressant (for prophylaxis of organ transplant rejection).

For new members, protected class drug logic will always override transition logic to process the claim. Additionally for new members, a 120-day transition period from their member start date is provided.

1.11 Member Notification

Sponsor will send written notice consistent with CMS transition requirements via U.S. first class mail to enrollee within three business days of adjudication of the temporary transition fill. If the enrollee completes his or her transition supply in several fills, the sponsor is required to send notice with the first transition fill only. The notice must include (1) an explanation of the temporary nature of the transition supply an enrollee has received;
(2) instructions for working with the plan sponsor and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan'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. 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. Sponsor will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review. Sponsor will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.

Providing written notification to the member and/or provider in accordance with CMS requirements is ultimately the responsibility of the Plan.

The Plan's PBM and their print vendor adhere to all CMS Marketing Guidelines as set forth in Chapter 2 of the Medicare Prescription Drug Benefit Manual.

Sponsor will make their transition policy available to enrollees via link from Medicare Prescription Drug Plan Finder to sponsor web site and include in pre-and post-enrollment marketing materials as directed by CMS.

1.12 PDE Reporting

Since this is a CMS required process, any drugs dispensed that qualify under the transition period are reported as covered Part D drugs with appropriate Plan and member cost sharing amounts on the Prescription Drug Event (PDE).

1.13 CMS Submission

Sponsor will submit a copy of its transition process policy to CMS.

1.14 Pharmacy and Therapeutics Committee Role

The Plan's PBM has a Pharmacy and Therapeutics Committee (P&T) that maintains a role in the transition process in the following areas:

1) The P&T committee reviews and recommends all formulary step therapy and prior authorization guidelines for clinical considerations; and
2) The P&T committee reviews and recommends procedures for medical review of non-formulary drug requests, including the exception process.

1.15 Exception Process

The Plan's PBM follows an overall transition plan for Medicare Part D members; a component of which includes the exception process. The Plan's PBM exception process integrates with the overall transition plan for these members in the following areas:

1) The Plan's PBM exception process complements other processes and strategies to support the overall transition plan. The exception process follows the guidelines set forth by the transition plan when applicable.
2) When evaluating an exception request for transitioning members, the Plan's exception evaluation process considers the clinical aspects of the drug, including any risks involved in switching, when evaluating an exception

request for transitioning members.

3) The exception policy includes a process for switching new Medicare Part D plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Sponsor will make 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 plan web sites.