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**Policy & Procedures**

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| **P&P #:** | 050-Pharmacy | **Page** 1 of 9 |
| **TITLE:** | Transition of Care Policy | |
| **APPROVED:** | 06/01/2025 | |
| **DEPARTMENT:** | Pharmacy | |
| **X MEDICARE** | **MEDI-CAL** | |

## 1. Policy

### 1.1 Overview

Astiva Health supports 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.

Astiva Health 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. Astiva Health 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 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

Astiva Health 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 co-ordinated 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

Astiva Health allows a transition period of 90 days from the start of coverage under a new plan. The 90 days are calculated from the beneficiary's start date. Astiva will extend the 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.

- For members that are new to the plan or that are re-enrolling but had a break in coverage, Astiva Health will set the transition start date to match the member's effective date.
- For existing (non-new) members that are assigned to a new group within the same health plan the default process will analyze the change in group number assignment to determine if it results in a new CMS contract and/or plan assignment.
    - If the change in group number resulted in a new CMS contract assignment, the member's transition start date will be updated to mirror the effective date of the group change.
    - If the change in group number did not result in a new CMS contract assignment, the member's transition start date will remain as is and will not be updated.
    - If the change in group number resulted in a new plan assignment and new formulary ID, the member's transition start date will be updated to mirror the effective date of the group change.
    - If the change in group number did not result in a new plan assignment or new formulary ID, the member's transition start date will remain as is and will not be updated.

Astiva Health 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: Astiva Health's PBM has systems capabilities that allow Astiva Health 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: Astiva Health's PBM utilizes the current NCPDP Telecommunication Standard to provide pharmacy industry standard POS messaging.

**c)** Edits During Transition: Astiva Health 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.

Astiva Health will ensure 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), Astiva Health 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 PBM Help Desk directly for immediate assistance with point-of-sale overrides. The 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

Astiva Health 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

Astiva Health 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.

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 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.

For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, the Astiva Health 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.

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

Astiva Health 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 PBM in order to provide continued coverage of the transition drug(s).

**1.9** Cost-sharing for Transition Supplies

Astiva Health 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

Astiva Health 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. 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 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. Astiva Health 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. Astiva Health will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.

Astiva Health 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

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

**1.14** Pharmacy and Therapeutics Committee Role

Astiva Health uses the PBM Pharmacy and Therapeutics Committee (P&T) which maintains a role in the transition process in the following areas:

1) The PBM P&T committee reviews and recommends all formulary step therapy and prior authorization guidelines for clinical considerations; and

2) Reviews and recommends procedures for medical review of non-formulary drug requests, including the exception process.

**1.15** Exception Process

Astiva Health follows an overall transition plan for members; a component of which includes the exception process. Astiva Health's exception process integrates with the overall transition plan for these members in the following areas:

1) Astiva Health's 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 plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Astiva health 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.

## APPENDIX A. GLOSSARY

| Term | Description |
|---|---|
| CMS | Centers for Medicare and Medicaid Services – The agency within the US Federal Government that is charged with the execution and maintenance of the law defining the prescription drug program for senior citizens, the disabled, and the infirm. |
| Emergency Supply | An Emergency Supply is defined by CMS as a one-time transition fill that is necessary with respect to members that are outside of their initial 90-day transition period and that are in the LTC setting. |
| FTP | File Transfer Protocol – One of the methods used by the PBM to transfer electronic files via the Internet. The first two bits of the file indicate the type of file. |
| HICL | A First Data Bank (FDB) data warehouse term that is an alpha-numeric code used to describe drugs ingredients. The HICL codes have been sequenced according to an ingredient sequence table. The HICL sequence table establishes relative importance to each ingredient, relative to other ingredients. The relative importance of an ingredient is based on its clinical and therapeutic use. The most important ingredients are sequenced first and the least significant are sequenced last. |
| Level of Care Changes | Level of care changes include the following changes from one treatment setting to another:<br>• Enter LTC facility from hospitals or other settings;<br>• Leave LTC facility and return to the community;<br>• Discharge from a hospital to a home;<br>• End a skilled nursing facility stay covered under Medicare Part A (including pharmacy charges), and revert to coverage under Part D;<br>• Revert from hospice status to standard Medicare Part A and B benefits; and<br>• Discharge from a psychiatric hospital with medication regimens that are highly individualized. |
| LTC | Long Term Care |
| NSDE | The FDA's Comprehensive NDC Structured Product Labeling Data Elements file. This file is used to provide structured product labeling of Brand and Generic drugs. |
| PA | Prior Authorization - The process undertaken to make a benefit determination that is made prior to the intended delivery of the healthcare service, treatment or supply under review (e.g., a Pre-Service Claim). Prior Authorization includes requests for coverage determination for medications that are designated on the client part D formulary as "Prior Authorization Required", "Step Therapy", "Quantity Restrictions" or for requests for exception for non-formulary medications or co-insurance amount. |
| PDE | Prescription Drug Event. File that reports all claims transactions to CMS for inclusion in the annual financial reconciliation between CMS and the Plans. |
| Plan | Astiva Health Medicare Part D Plan |
| POS | The acronym given to the PBM's point-of-sale prescription transaction processing computer system. Also indicates that the actual retail transaction occurs when the claim is submitted electronically by the pharmacy. |
| P&T Committee | Pharmacy & Therapeutics Committee – An independent group of external & internal health care practitioners that are responsible for evaluating the efficacy, safety and cost effectiveness of medications to determine potential additions, subtractions and other changes to a formulary. |

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| UM | Utilization Management – A set of guidelines that can be applied independently or jointly that otherwise restrict access to the dispensing or consumption of prescription drugs. The four basic restrictions are prior authorization (PA), quantity limits (QL), step therapy (ST) and tier placement. UM is a tool used by health plans to ensure safe, efficacious and cost- |