CMS CONTRACTS: H3954, H3924, H9412

Geisinger Policy & Procedure Manual	Policy: 76.0D Section: Pharmacy Subject: Part D Medication Transition Policy

Applicable line of business

Commercial		Medicaid	
Medicare	X	ACA	

I. POLICY

Geisinger Health Plan (GHP) provides an appropriate transition process to ensure that all eligible Medicare Part D GHP members are provided a transition process that is in compliance with established CMS transition guidelines. The transition process requires that all eligible members have immediate access to most Part D eligible prescription drugs.

GHP's transition policy applies to Part D covered drugs that are not on the formulary, or previously approved for coverage under an exception once the exception expires, and Part D covered drugs that are on the formulary but require prior authorization or step therapy or that have an approved quantity limit lower than the member's current dose, under utilization management rules. (CMS Attestation #3)

A copy of this transition policy shall be submitted to the Centers for Medicare and Medicaid Services (CMS) as required by regulation. (CMS Attestation #2)

II. RESPONSIBILITY

Medicare-designated staff within the Geisinger Health Plan Pharmacy Department.

III. REQUIRED DEFINITIONS

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.

2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.

3. Devised – the date the policy was implemented.

4. Revised – the date of every revision to the policy, including typographical and grammatical changes.

5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

IV. ADDITIONAL DEFINITIONS

1. New Member – A member who has not historically been an established member of the health plan and who has become eligible for benefits for the first time with the Plan.
2. Existing Member – A member who has been an established member of the Plan and continues enrollment with the Plan.

V. TRANSITION BACKGROUND (CMS Attestation #3, #12)

CMS requires all plans offering a Prescription Drug Benefit to provide an appropriate transition process applicable to non-formulary drugs, including Part D drugs that are not on a sponsor's formulary and Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a plan's utilization management rules.

Geisinger Health Plan's exception process integrates a transition for members by following the exception process set forth by the transition plan when applicable. When evaluating an exception request for transitioning members, the Health Plan's exception evaluation process considers the clinical aspects of the drug, including any risks involved in switching. The exception policy addresses procedures for medical review of non-formulary drug requests and when appropriate, includes a process for switching new Medicare Part D plan members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

Geisinger Health Plan 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.

The prescriber's supporting statement for medical review of non-formulary drug requests should include documentation of an FDA approved or compendia supported indication and a therapeutic failure on, contraindication to, or intolerance to formulary alternatives (if available).

When the supporting statement is not supplied to the plan the plan will fax a Clinical Criteria Form to the prescriber with a request for a written supporting statement and any additional documentation the provider may wish to submit to support the coverage determination request. Additionally, the plan will make, at a minimum, two attempts to contact the prescribing provider via telephone to obtain their supporting statement. Once the written supporting statement has been received, a decision will be made within appropriate timelines. If no supporting statement is received, a determination is made based on available information.

If the coverage determination is denied, the prescriber and enrollee (or enrollee's authorized representative) will be verbally notified of the adverse determination and both will also be sent a written confirmation of adverse determination. The verbal and written notifications will include the specific reason for the adverse determination, formulary alternatives (if appropriate), as well as instructions for initiation of the Appeal process.

Situations may arise where GHP members may not be aware of the medications covered on Geisinger's formulary or are unfamiliar with Geisinger's formulary exception process. Consistent with 42 CFR § 423.120(b)(3), Geisinger Health Plan has established a process to effectuate a meaningful transition for both new and existing members affected by these and other similar scenarios.

VI. PROCEDURE

1. Transition Population (CMS Attestation # 1)

To ensure uninterrupted drug therapy the transition process is necessary with respect to Medicare Part D members in a number of scenarios. The transition process applies to the following members:

- New Members into prescription drug plans following the annual coordinated election period
- Newly eligible Medicare beneficiaries from other coverage
- Individuals who switch from one plan to another after the start of a contract year
- Members residing in LTC (Long Term Care) facilities
- Current members affected by negative formulary changes across contract years

2. Pharmacy and Therapeutics Committee Role

Annually the Pharmacy and Therapeutics (P&T) Committee will review the formulary negative changes. The P&T Committee will address situations where the member is stabilized on the non-formulary drug or drugs that now require prior authorization or step therapy and make appropriate transition recommendations when there are known risks with any changes in the prescribed regimen.

3. Implementation Statement

a) **Claims Adjudication System:** GHP's Pharmacy Claims Processor's system has systems capabilities that 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:** Our claims processor utilizes the current NCPDP Telecommunication Standard to provide POS messaging. Point-of-sale notification goes to the pharmacy at time of adjudication with messaging that may be passed to the member regarding a drug's coverage status. The transition messaging is transmitted to pharmacies in a retail setting (including home infusion, safety-net and I/T/U pharmacies) as well as pharmacies in a LTC setting. The transition messaging is passed in the proper messaging fields as specified by CMS and NCPDP standards.

c) **Edits During Transition:** GHP**'s** Pharmacy Claims Processor will only apply the following utilization management edits during transition at point-of-sale: edits to determine Part A or Part B versus Part D coverage, edits to prevent coverage of non-Part D drugs or indications, and edits to promote safe utilization of a Part D drug. Step therapy and prior authorization edits must be resolved at point-of-sale.

   GHP**'s** Pharmacy Claims Processor's system will provide refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.

d) **Pharmacy Overrides at Point-Of-Sale:** During the member's transition period, all edits (with the exception of those outlined in c. above) are automatically overridden by GHP's Pharmacy Claims Processor's claims adjudication system at the point-of-sale. Pharmacies can also contact GHP's Pharmacy Help Desk directly for immediate assistance with point-of-sale

override resolution as necessary 24 hours a day, 7 days a week. Transition medications are automatically overridden and process at point of sale. Notification also goes to the pharmacy at the time of adjudication with messaging that may be passed to the member regarding the drug's coverage status.

4. Utilization Edits and Pharmacy Access to Transition Drugs (CMS Attestation #4, #8)

GHP will accommodate the immediate needs of its members by ensuring that all edits resulting from changes in GHP's formulary between contract years and members impacted will automatically be overridden by our Pharmacy Claims Processor's claims adjudication system as a transition fill at point-of-sale. GHP's Pharmacy Claims Processing system also provides messaging to the pharmacist when the claim was filled as a transition process fill.

During the transition period, the following edits will continue to be applied at point-of-sale by our claims adjudication system as follows:

i. Edits to help determine Part A or B vs. Part D coverage;
ii. Edits to prevent coverage of non-part D drugs (i.e., excluded drugs) or indications (i.e.,Transmucosal Immediate Release Fentanyl (TIRF) and Cialis); and
iii. Edits to promote safe utilization of a Part D drug (i.e., quantity limits based on FDA maximum recommended daily dose; early refill edits).

Step therapy and prior authorization edits will be resolved at point-of-sale

5. Transition Timeframes and Temporary Fills (CMS Attestation #4, #9)

Anytime within the first 90 days of coverage under a new plan, GHP will provide a temporary fill when the new member fills a prescription for a non-formulary drug or Part D drug that is on Geisinger's formulary but requires prior authorization or step therapy. The Pharmacy Claims Processor's claims adjudication system will automatically allow a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of a member, as well as to allow the plan and/or the member 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. Existing members taking drugs impacted by a negative formulary change (move to non-formulary status or addition of prior authorization or step therapy) will also be eligible for a transition fill. If transition prescriptions are dispensed for less than the written amount because the drug is subject to quantity limit safety

edits or drug utilization edits that are based on approved product labeling, refills (multiple fills) will be provided. This 90-day time frame applies to retail, home infusion, long-term care, and mail-order pharmacies.

Transition fills for Members in the Outpatient (Retail) Setting

In the retail setting, anytime within the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage, the new member can obtain at least a one-time, temporary fill of at least a month's supply of medication (unless the prescription is written for less than a month's supply in which case multiple fills will be allowed to provide up to a total of a month's supply of medication). This process automatically occurs at point of sale through GHP's Pharmacy Claims Processor's claims adjudication system. (CMS Attestation #5)

Transition fills for members in the Long Term Care (LTC) Setting: (CMS Attestation #7)

In a long-term care setting, (1) the transition policy provides for a one time temporary fill of at least a month's supply (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; (2) after the transition period has expired, the transition policy provides for a 31-day emergency supply of a non-formulary Part D drug (unless the prescription is written for less than 31 days) while an exception or prior authorization is requested; and (3) for members 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.

During the 90-day transition period, transition fills for members in a long term care setting process automatically at point of sale through GHP's Pharmacy Claims Processor's claims adjudication system.

For a member who is a resident of a long-term care facility and has been enrolled in Geisinger Health Plan for more than 90 days, and needs a non-formulary drug or a drug subject to other restrictions (such as step therapy or prior authorization), Geisinger will cover a temporary 31-day emergency supply of that drug (unless the prescription is for fewer days) while an exception or prior authorization is requested. LTC pharmacies are permitted

to use Emergency Boxes (E Box) when necessary. In order to receive the 31-day emergency supply, the LTC pharmacy must call GHP Pharmacy Services Customer Service and request the emergency supply. There is no way to allow this process to occur automatically at point of sale.

GHP will apply all transition processes for a non-formulary drug if it cannot distinguish at point-of-sale (POS) between a new prescription for a non-formulary drug and an ongoing (refill) prescription for a non-formulary drug. (CMS Attestation #10)

GHP will make arrangements to continue to provide necessary Part D drugs to members 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) to ensure that members have access to necessary Part D drugs. (CMS Attestation #15)

Transition Across Contract Year **(CMS Attestation #16)**

Geisinger may change its formulary for an upcoming contract plan year. For current members whose drugs will be affected by negative formulary changes in the upcoming year, GHP 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.

GHP's Pharmacy Claims Processor's 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 (changes to a formulary that result in a potential reduction in benefit to beneficiaries, i.e. removing the covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management) from one plan year to the next.

GHP will extend the transition policies across contract years should a beneficiary enroll into the plan with an effective date of either November 1 or December 1 and require access to a transition supply. (CMS Attestation #13)

6. Cost Sharing for Transition Supply. (CMS Attestation #6)

Cost-sharing for a temporary supply of drugs for low-income subsidy (LIS) members will not exceed the statutory maximum co-payment amount for LIS eligible members. Cost-sharing for a temporary supply for non-LIS members will be based on the appropriate cost-sharing tier as normally charged for non-formulary Part D drugs approved through a formulary exception process 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. Notification to Members and Providers (CMS Attestation #11)

On a daily basis, GHP's claims processor will review the point-of-sale overrides that indicate that a transition supply was dispensed in order to determine whether a transition notice is needed. If so needed, the claims processor will generate and send the transition notice. This file includes the necessary member, prescriber, and claims data for members who received a transition fill the previous day. GHP makes reasonable efforts to notify prescribers of affected members who receive a transition notice by sending the prescriber a transition notice. Member and prescriber letters are generated simultaneously and sent via U.S first class mail within 3 business days of a temporary transition fill. For LTC residents dispensed multiple supplies of a Part D drug in 14-day or less increments the written notice will be provided within 3 business days after adjudication of the first temporary fill.

GHP uses the CMS model Transition Notice submitted to CMS via the file-and-use process.
The member and prescriber notices include:

1. An explanation of the temporary nature of the transition supply that the member has received;
2. Instructions for working with GHP and the member'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 member's right to request a formulary exception; A description of the procedures for requesting a formulary exception

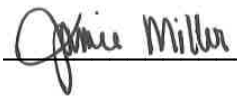
GHP ensures through daily audits that the print vendor sends written notice via U.S. first class mail to member **and** prescriber within three business days of a transition fill.

8. Public Notice of Transition, Prior Authorization, & Exception Process (CMS Attestation #14)

GHP provides general information about the transition process to members through various methods including; plan pre- and post-enrollment materials such as the Evidence of Coverage and formulary; facsimile or email, upon request; the plan website; and, the required link from the Medicare Prescription Drug Plan Finder to the GHP website.

This policy will be maintained in compliance with the standards of any other applicable state and federal regulatory entities.

This policy will be revised as necessary and reviewed no less than annually by the P&T committee.

Signature: 

Title: Director of Pharmacy

Date: 06/01/22

Developed: 07/05

Revised: 02/06 cosmetic and grammar changes Revised: 08/06 added 31 day emergency supply on to LTC section and deleted Greg's name, Revised: 10/06 deleted Greg's name and replaced with Dr. Davis, Reviewed: 12/06 annual review, Revised: 05/07 – changed signature & title, Reviewed: 12/07 – annual review, Revised: 06/08- updated to state that auths will be entered electronically via Argus and referenced the Argus document on Transition authorization., Revised: added last bullet on uploading the reporting requirements into HPMS., Revised: 11/08-updated annual review of website posting and clarified data upload process, Reviewed: 12/08 – annual review, Reviewed: 12/09- annual review, Revised: 06/10 – CMS required changes with references to attestations, Revised: 12/10 – CMS required change in prescriber notification, Reviewed: 12/10, Revised: 04/11 – Added D.O messaging language, Revised: 11/11 – grammatical and annual review, Revised: 03/20/12 – revised by Attac for accuracy in 2012, Revised: 11/07/12, Revised: 03/29/13 – revised to include E Box, Revised & reviewed: 05/16/13 add Attestation 12, changed day supply to 31, and annual review, Reviewed: 10/13, Revised: 05/15/14 – changed retail day supply to 30, changed Director of Pharmacy signature, and annual review, Revised: 05/23/14 – updated attestation #6 per CMS email received 5/23/14, Revised: 07/07/14 – updated to address CMS areas of concern, Revised: 06/01/15 – updated for CY2016 submission, added POS language, Reviewed: 06/01/16 – annual review, Reviewed: 06/01/17 – annual review, Reviewed 06/01/18 – annual review, 06/01/19 – annual review, 06/01/20 – annual review, 06/01/21—annual review & changed e-box language, 06/01/22—annual review