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CY 2024 Transition Process Policy

The CY 2024 Transition Process Policy applies to the following CMS contracts: H5106, H3916, S5593, H3957, H8166, H3384, H5526, and S1140.

Introduction

Highmark maintains 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. This 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. Transition is effectuated in the following situations:

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

Clinical Review

The transition process will ensure that beneficiaries have uninterrupted access to Part D drugs that allows them a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of the 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. Providers and enrollees may request coverage of a non-formulary drug or a drug that requires prior authorization under the plan's utilization management rules by (1) completing the plan's Prescription Drug Medication Request Form (or submitting any documentation requesting a coverage determination) and faxing it to the plan (fax number listed on the form), (2) completing the plan's Prescription Drug Medication Request Form (or submitting any documentation requesting a coverage determination) and mailing it to the plan (plan address provided with the form), (3) calling a dedicated line and speaking with a provider representative who can facilitate the clinical review process, or (4) complete a request electronically (if equipped with the hardware and software to do so). The coverage request will be received in accordance with Highmark's clinical review process. Letters are provided to the provider and enrollee detailing the outcome of the clinical review of their coverage request and their appeal rights. In the event of a negative determination for the enrollee, therapeutically appropriate alternatives are

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detailed in the provider letter. The plan's Prescription Drug Medication Request Form outlines procedures for obtaining plan formulary information. Prescription drug medication request forms, which can be used for prior authorization and exception requests, are available to providers and enrollees through a variety of mechanisms including by US mail, fax, e-mail, or electronically via the plan's website.

The transition process includes components of beneficiary and provider education and outreach, an established non-formulary request process, an established prior authorization request process, and temporary one-time supply fills to allow sufficient time to review a medication request or conversion to an appropriate formulary alternative. The medication request process and the criteria used to review requests are reviewed and approved by the practicing physicians and pharmacists on the Highmark Pharmacy and Therapeutics Committee. The criteria and policies are reviewed and approved at least annually or more frequently if changes are necessary.

The claims processing system used to administer Highmark's transition process allows auto-effectuation at the point-of-sale to temporarily override non-formulary and prior authorization edits to ensure a smooth transition process and accommodate the immediate needs of the enrollee. In addition, the transition process permits time for the enrollee and their prescriber to collaborate and switch to a therapeutically equivalent medication or submit a request to maintain coverage of the existing medication.

Only the following utilization management edits will apply 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 the safe utilization of Part D drugs. Step therapy and prior authorization edits will be resolved at point-of-sale via transition fill, if not otherwise listed above.

In maintaining compliance with the goals intended in the messaging guidance, the plan will work with its claims processing vendor to implement appropriate systems changes to achieve the goals of any additional new messaging approved by the industry to address clarifying information needed to adjudicate a Part D claim. Any alternative approaches used will remain in compliance with the goals intended in the messaging guidance.

Implementation Statement

Administered through its claims processing vendor, Highmark's adjudication process that supports transition supply requirements is as follows:

1. A mail-order, retail or long term care (LTC) pharmacy receives a prescription request from:
 - a. New enrollees into its prescription drug plans following the annual coordinated election period;
 - b. Newly eligible Medicare beneficiaries from other coverage;
 - c. Enrollees who switch from one Plan to another after the start of a contract year;
 - d. Current enrollees affected by negative formulary changes across contract years;
 - e. Enrollees residing in LTC facilities;

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- f. In some cases, enrollees who change treatment settings due to a change in level of care.
 - g. Enrollees who are undergoing a change in care are eligible for a temporary supply to ensure the continuity of needed medications across care settings. If the enrollee is not in their transition period during their care change, or is in the transition period but has already received their transition supply days supply maximum, the system will reject the claim and appropriate reject codes are returned to the pharmacy. Express Scripts provides additional secondary messaging (If Level of Care) and training to inform the network pharmacy of the appropriate procedure. In the circumstance where an enrollee is changing care setting and may not have access to current prescriptions, the network pharmacy may contact the Express Scripts help desk for an override to dispense a temporary transition fill. Appropriate transition notifications are generated to the enrollee and the prescriber in the required timetable. As these enrollees are vulnerable to disruption in care, Express Scripts also provides daily rejected claims data to the Plans for oversight of these enrollees experiencing a change in their care to assure the transition has been effectuated.
2. The pharmacy submits the prescription request and the drug is either non-formulary or on the formulary but with utilization management edits applied.
3. The process verifies that the beneficiary is enrolled in a Part D plan.
4. Verification that the enrollee is within a transition window occurs by interrogating their available Part D eligibility history.
5. The process verifies that the drug submitted qualifies for a transition supply based on the reject messaging triggered. The rejects indicate one of the four transition eligible categories:
 - a. Non-Formulary;
 - b. PA Required;
 - c. Step Therapy rules;
 - d. Quantity rules.
6. The process determines the allowable day supply for a transition fill.
7. The process verifies that the beneficiary is eligible for a transition supply of the drug based on the date of service on the claim falling within their transition window.
 - a. The system determines potential LTC emergency fill scenarios. An automated process is in place to automatically pay emergency supply claims. If an LTC enrollee is outside of a transition window and presents a transition-eligible prescription drug request, an emergency transition supply of up to 31 days will be paid.
8. A current enrollee is eligible when a paid claim is found within the last 120 days of the previous plan year for the same drug (HICL/route) within the same CMS Contract ID and the history claim did not pay under transition logic.

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9. Using the submitted day supply from the claim, the process will verify that the claim is within the transition day supply limit or has remaining transition day supply to be dispensed.
 - a. Transition claims will be limited to the transition day supply limit established unless it is a prepackaged drug and cannot be dispensed lower than the transition day supply. Refills may be allowed on transition claims up to the point where the transition day supply obligation has been met or exceeded by the last fill.
 - b. When greater than the allowable day supply limit, the claim will hard reject and a message will be returned to the pharmacy noting the allowable day supply/quantity for a transition fill. The pharmacy is then notified to resubmit the claim within the limits presented in the message.
10. If a previous transition supply of the same drug was already dispensed within the same transition period, the system will verify whether a refill is allowable based on the previous days supply already dispensed.
11. If a required full transition supply was found to have already been provided to the enrollee while in their transition period, the system will hard reject the claim and return an If Level of Care message to the pharmacy with instruction to contact the pharmacy help desk to determine if the enrollee is eligible for a level of care fill.
12. Cost-sharing will be calculated for the transition supply based on the plans benefit requirements. For plan benefits where all enrollees are low income subsidy eligible, the copay is tiered to Brand or Generic LICs levels or, if specified, the Part D drugs are tiered to \$0 dollar cost sharing in line with the CMS LICs waiver for Plan.
13. The process will successfully adjudicate the claim and send a message to the pharmacy with a paid response of either “PAID AS TRANSITION FILL” or “PAID AS EMERGENCY SUPPLY” depending on the type of adjudication which was completed.
14. The required enrollee notifications are mailed within three business days of adjudication of the first fill of a transition supply. Mail notifications for refills of a transition supply are not generated.
15. The required prescriber notifications are faxed or mailed within five business days after the first fill of a transition supply if we are able to locate valid prescriber contact information in one of the national prescriber databases utilized.
16. The adjudication process described above is configured to automatically pay a claim for an eligible medication when an enrollee is in their transition period, or as a result of the enrollee needing an LTC emergency supply. If an enrollee is changing care setting and may not have access to current prescriptions, the network pharmacy may contact the help desk for an override to dispense a temporary transition supply. Additional secondary messaging (If Level of Care) and training are provided to inform the network pharmacy of the appropriate procedure to allow a level of care override.
17. If an enrollee is in need of an extension to the transition supply they can reach out to their plan in advance or at POS to request an extension. Network pharmacies are

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aware of the potential need for an extension while the enrollees prescriber or plan are resolving the exception or PA needed for their medication. The network pharmacy may call the help desk to get an override for an additional transition supply in this circumstance. This final manual step enables transition eligible non-formulary, quantity, step therapy and PA edits to be resolved at POS.

Highmark's adjudication process described above, which supports transition supply requirements from CMS, will *automatically* pay a claim barring certain instances where a hard reject is returned that require the pharmacy to take action before resubmitting the claim and achieving a paid transaction.

As recognized in CMS guidance, certain edits may exist where a hard reject is returned that requires the pharmacy to take action before resubmitting the claim and achieving a paid transaction. When an edit is in place that triggers the hard reject of a transition eligible claim for a transition eligible enrollee, the pharmacy is required to take steps in order to achieve a paid transaction. The steps required by the pharmacy are included in the associated messaging returned at POS. Training and documentation on these processes is included in the Express Scripts Network Manual to support timely determinations. In addition to limited safety editing, the hard reject messaging conditions that may be triggered during adjudication of a transition supply eligible claim are:

1. Plan Limitations Exceeded
When this message is returned, the pharmacy is required to modify the submitted quantity to be equal to or less than the amount included in the POS message. Upon resubmission with corrected information, the transition supply claim will pay and be marked as a transition supply.
2. If Level of Care Change Call Help Desk
When this message is returned, the pharmacy is required to contact the Pharmacy Help Desk. A process is in place with the Help Desk and includes a series of questions that are posed to the pharmacy. If any of the questions are answered with YES, then a level of care change is confirmed. The Help Desk provides override codes to the pharmacy to place on the claim and the pharmacy is asked to resubmit. Upon resubmission with the override codes the claim will pay and be marked as a transition supply.
3. Refill Too Soon (RTS)
To limit inappropriate or unnecessary access to Part D drugs, an early refill edit will trigger a hard reject for a transition eligible drug during an enrollee's transition period. The Highmark RTS logic considers paid claims, both mail and retail, for the same drug,

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dispensed in the previous 180 days to calculate an on-hand days' supply. The pharmacy may resubmit a claim with therapy change overrides for RTS at point-of-sale but limits the override use to 2 within 180 days. Other RTS requests (e.g., additional therapy change, vacation supply, lost medication, etc.) are managed by Highmark internal processes.

The Highmark RTS allowance requires that a beneficiary has consumed 70% of their drug on-hand of an ophthalmic agent as well as at least 75% of any other medication.

4. Med B/D Determination Required

B/D overlap drugs are excluded from Transition Supply processing by Medicare law as the determination must be made prior to adjudication for appropriate billing. Messaging returned to the pharmacy indicates this need for verification by sending the message: "B/D Determination Required". Training and documentation on these processes is included in the Express Scripts Network Manual to support timely determinations.

5. Part A versus Part D Determination Required

For beneficiaries who have elected the Medicare hospice benefit, drugs in the four hospice categories are excluded from the transition process, as payer determination must be made prior to adjudication for appropriate billing. Messaging returned to the pharmacy indicates this need for verification by sending the message: "Prior Authorization is Required; This product may be covered under Hospice – Medicare Part A". Additional secondary messaging includes: "Member Enrolled in Hospice; Hospice provider – request Prior Authorization. Call for review if not Hospice/Unrelated."

6. Med D/non D Determination Required

D/non-D drugs are excluded from Transition Supply processing by Medicare law as the determination must be made prior to adjudication for appropriate billing. Messaging returned to the pharmacy indicates this need for verification by sending the message "Med D/Non-D Determination Req".

7. Short Cycle Fill (SCF)

To comply with CMS guidance related to the LTC pharmacy requirement to dispense certain Part D drugs in small increments, various edits exist that may trigger a hard reject for an enrollee during a transition period. All SCF related hard rejects occur prior to transition supply processing and are required to be cleared by the LTC pharmacy before the claim will automatically pay as a transition supply. Once the SCF edits are cleared and a paid transition supply claim is adjudicated, the pharmacy receives one of the two paid claim messages of "PAID AS TRANSITION FILL" or "PAID AS EMERGENCY SUPPLY". Subsequent transition fills will be allowed up to the days supply set by the Plan.

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8. Opioid Medication Quantity Limits

To comply with CMS requirements to limit opioid medications to appropriate quantities, there are hard edits that enforce predetermined quantity limits for opioid medications. A temporary supply of opioids with a related plan level limit will transition. Opioid quantity level limits for safety purposes, such as Morphine Milligram Equivalent (MME) quantity limits and enrollee-specific limits must be resolved before the claim will be considered for transition.

Communications

Prior to enrollment in the plan and on an ongoing basis during enrollment, Highmark will include the transition policy in plan marketing materials, as directed by CMS. Further, the transition policy will be available to potential and current enrollees via a link from the Medicare Prescription Drug Plan Finder to the plan web site.

Highmark will send written notice consistent with CMS transition requirements. Within 3 business days of the administration of a temporary supply fill, the plan will provide the following information to the affected enrollee in a CMS-approved non-model transition notice written communication delivered via US first class mail:

1. An explanation of the temporary nature of the transition supply of drug the enrollee has received.
2. Instructions for working with the plan sponsor and the prescribing provider to satisfy utilization management criteria or to identify appropriate therapeutic alternatives that are available on the plan's formulary.
3. An explanation of the enrollee's right to request a formulary exception.
4. A description of the procedures for requesting a formulary exception, including how to obtain a Prescription Drug Medication Request Form.

For long term care residents dispensed multiple supplies of a Part D drug in increments of 14-days-or less, the aforementioned written enrollee communication will be provided within 3 business days of the adjudication of the first temporary supply fill.

Transition Supply Fills

In the event that, during a beneficiary's transition window, an enrollee presents to the pharmacy with a prescription for a non-formulary drug or a drug that requires prior authorization according to the plan's utilization management rules, the transition policy will apply and a temporary supply fill will be provided. This process will allow adequate time to coordinate with the prescriber for the submission and review of an exception or prior authorization request, or transition to a formulary alternative without interruption of the beneficiary's drug therapy. A transition fill may occur anytime during the first 90 days of beneficiary's enrollment in a plan (including current

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enrollees who enter a new contract year), beginning on the enrollee's effective date of coverage. For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, a meaningful transition will be effectuated 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. For current enrollees whose drugs will be affected by a negative formulary change in the upcoming year, claims will be transition eligible when a paid claim is found within the last 120 days of the previous plan year for the same drug (HICL/route) within the same CMS Contract ID and the history claim did not pay under transition logic. For new enrollees, if the plan is at any time unable to make a 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, the transition process criteria that apply to a brand-new prescription for a non-formulary drug will apply.

Messaging will be provided to the dispensing pharmacist at the point of sale that identifies the claim as a one-time temporary fill. The completion of this transaction will trigger a notice to the plan that the one-time temporary supply was provided. The plan will then send a targeted letter to the beneficiary notifying them about the transition process, the plan formulary, and how to initiate the exception process. The plan will also send a targeted letter to the provider with the same information notifying them of their role in assisting the enrollee with the transition process.

Retail/Mail Considerations

In retail and mail settings, the first time a new enrollee presents a prescription for a non-formulary drug or a drug that requires prior authorization according to the plan's utilization management rules, a one-time, temporary fill of at least a month's supply of the drug will be provided with the appropriate enrollee cost share (copay, coinsurance, or deductible) applied. If the prescription is written for a day supply less than a month, the plan will allow multiple fills that provide up to a total of one month of medication therapy anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage. For temporary supply fills that are 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, the transition process will allow for refills up to a total of at least one month supply of the Part D drug.

Long-Term Care Considerations

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

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enrollees are allowed to access a refill upon admission or discharge. Such supplies are available, when appropriate, from retail, mail order, or home infusion pharmacy providers.

Transition Period Extensions

An extension of the transition period will be granted, on a case-by-case basis, to the extent that the plan has been unable to process an enrollee's exception request or appeal 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).

The transition period will be extended across contract years should a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1, and require access to a transition supply. The enrollee will receive a transition fill when a paid claim is found within the last 120 days of the previous plan year for the same drug (HICL/route) within the same CMS Contract ID and the history claim did not pay under transition logic for a drug that has changed formulary status, is newly subject to prior authorization, or is newly subject to quantity limit. Transition will also be provided for those enrollees with effective enrollment date of either November 1 or December 1 when newly receiving a drug that is not on the formulary or to which prior authorization applies when they have not previously exhausted the transition supply for that medication.

Cost Sharing

For each temporary supply of drug provided to an enrollee, the appropriate cost-share will be applied (copay, coinsurance, or deductible). The cost-sharing 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.