n04231

Medicare Part D Transition and Emergency Fill Policy

Values

Accountability ● Integrity ● Service Excellence ● Innovation ● Collaboration

Abstract Purpose:

The Medicare Part D Transition and Emergency Fill Policy defines how Network Health Insurance Corporation (NHIC) or their delegate will provide a Transition Fill Process for Medicare Part D beneficiaries, which allows certain members to obtain non-formulary Part D drugs (or drugs subject to requirements/limits). Additionally, this policy defines a procedure to ensure member access to Part D drugs during an emergency. The Transition and Emergency procedures are defined in accordance with the Centers for Medicare and Medicaid Services (CMS) guidance, meet the CMS requirements, and are reviewed annually. This policy applies to beneficiaries as defined.

Scope: This Policy is applicable to the NHIC Prescription Drug Plan and its enrollees covered under CMS contract H5215 and H5644.

Policy Detail:

NHIC, or their delegate, will provide a Transition/Emergency Fill Process for Medicare Part D beneficiaries to obtain non-formulary Part D drugs or drugs subject to requirements/limits, as well as a procedure to ensure access to Part D drugs during an emergency. This process will support decreased member disruption and will meet the CMS requirements.

Definitions

I. Transition Eligible Claims

   A. The applicable drug(s) must be non-formulary:

      1. Part D drugs not on the formulary

      2. Part D drugs that are on the formulary, but require prior authorization or step therapy, or are subject to quantity limits under utilization management rules

   B. The drug must be an otherwise Part D eligible drug

   C. The member must be Part D eligible

D. The beneficiary must be one of the following:

1. Newly enrolled to the plan following the annual coordinated election period, and during the first 90 days of enrollment, beginning on the effective date of coverage.
2. Newly eligible to Medicare transitioning from other coverage at the beginning of the calendar year, and during the first 90 days of enrollment, beginning on the effective date of coverage.

3. Transitioning from one plan to another after the start of the calendar year and during the first 90 days of enrollment, beginning on the effective date of coverage. For members needing access to a transition supply who are new at the end of the calendar year with an effective enrollment date of either November 1 or December 1, the transition period will extend across contract years.

4. Residing in a long-term care facility; and

   a. Within the first 90 days of enrollment, beginning on the effective date of coverage; OR

   b. In need of an emergency supply after the 90-day transition period has expired; OR

   c. Entering a LTC facility from another care setting, including after the initial enrollment period.

   d. Experiencing a level of care change and in need of access to early refills upon admission or discharge

5. Currently enrolled but affected by a formulary change from one calendar year to the next, for example drugs no longer on the formulary, or drugs remaining on the formulary but to which new prior authorization or step therapy restrictions apply. For these current enrollees who are affected by a formulary change at the beginning of a contract year, NHIC will effectuate a meaningful transition period at the beginning of the calendar year by providing a process consistent with the process required for new enrollees beginning in the new contract year.

II. Emergency Area: NHIC or their delegate will monitor for emergency situations defined as the following

A. The President has declared a major disaster,

B. The Secretary of the Department of Health and Human Services has declared a public health emergency, or

C. A Stafford Act or National Emergencies Act has been declared

Procedure Detail:

I. General Process/Overview of Transition: NHIC, or their delegate, maintains system capabilities implemented during the adjudication process to provide a temporary supply of non-formulary Part D drugs or Part D drugs that are on the plan's formulary, but are subject to utilization management rules (Prior Authorization Required, Step Therapy or Plan-imposed Quantity Limits) in order to accommodate the immediate needs of the enrollee. This process will allow NHIC and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or complete an exception request to maintain coverage of an existing drug based on medical necessity reasons. A series of soft edits will allow Medicare Part D eligible drugs to adjudicate at the point-of-sale, allowing a temporary fill of a non-formulary or restricted/limited drug subject to prior authorization step therapy or quantity limits to beneficiaries who are new to the plan or to current enrollees affected across contract years. NHIC will also provide refills for transition prescriptions that were dispensed for less than the written amount due to quantity limits for safety purposes, Short Cycle Fill requirements or drug utilization edits that are based on approved product labeling. The transition process will be allowed anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.

II. Transition Fills for Retail, Home Infusion, Mail Order, and I/T/U Setting

A. For each drug that is transition eligible, NHIC will cover a single fill or multiple fills up to at least a temporary minimum one-month supply (unless the enrollee presents with a prescription written for less than a one-month supply or the minimum transition fill allowed). If the enrollee presents with a prescription written for less than a one month or the minimum transition fill allowed, NHIC or their delegate will allow multiple fills to provide up to a total of at least a one-month supply of medication. In some cases when a drug is prepackaged and cannot be dispensed at a lower day supply, more than the minimum one-month supply may be dispensed.

B. After the initial minimum one-month supply or total amount of the prescription, NHIC will not cover further transition fills, even if the member has been in the plan less than 90 days.

III. Transition Fills for Long-Term Care

A. For each drug that is transition eligible, NHIC will ensure that in the long-term care setting, we will provide a one-month temporary fill consistent with the dispensing increment (unless the enrollee presents with a prescription written for less) with refills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the re-enrollee's effective date of coverage. If the enrollee presents with a prescription written for less than the minimum transition fill allowed, NHIC or their delegate will allow multiple refills as necessary, up to a one-month supply consistent with the filling increment during the first 90 days of a beneficiary's enrollment in the plan, beginning on the enrollee's effective date of coverage.

B. More than one refill of transition eligible drugs will be allowed for LTC residents, provided the fills are obtained within the initial 90 days of eligibility.

C. If the drug is subject to Short Cycle Fill (SCF) guidance, recurring fills of up to a 14-day supplies will be dispensed throughout the enrollee's transition window.

IV. Transition Notice

A. After receiving the temporary transitional fill, NHIC or their delegate will send written notice consistent with CMS transition requirements. A written CMS approved notice is sent via USPS First Class Mail to NHIC's enrollee within three business days of adjudication of a temporary fill. The transition fill notice will include:

1. An explanation of the temporary nature of the transition supply that the enrollee has received;
2. Instructions for working with NHIC and/or the enrollee's prescriber to either identify appropriate therapeutic alternatives on the formulary and obtain a new prescription for a formulary or unrestricted/unlimited product, or initiate a coverage determination or exception request for a non-formulary or restricted/limited drug, or satisfy utilization management requirements;
3. An explanation of the enrollee's right to request a formulary exception;
4. A description of the procedures for requesting a formulary exception, which includes expected timeframes to decision the request, and information on the right to appeal.

B. NHIC or their delegate will ensure reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice. NHIC or their delegate will send prescriber notifications with a fax notification, followed by mailing a written notification if faxing is not successful; typically, the letter is sent within five business days of the adjudication date of a transition supply dispensed to their patient. The prescriber notification utilizes a separate letter for the prescribing physician notifying them of the transition supply obtained by the enrollee.

C. There are circumstances in which notifications cannot be mailed to either an enrollee or a prescriber. Those circumstances include enrollees for whom the Plan or ESI does not have an approved USPS mailing address on file, or valid prescriber contact information despite ESI accessing multiple national prescriber databases. In these situations, ESI produces both member and prescriber drop files each business day to facilitate plan action and outreach. Prescribers that may have a transient address, or situations where the transition claim has been reversed prior to the notification being generated, would not result in a transition letter being sent. Monitoring of daily reject reports and letter reports support the enrollee experience for this potential circumstance.

D. 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 business days after adjudication of the first temporary fill.

V. Requests for Extensions, Exceptions or Authorizations

A. NHIC will, on a case-by-case basis, make arrangements to continue to provide necessary Part D drug coverage to members via an extension of the transition period 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 is reached regarding an exception request.

B. NHIC, or their delegate, 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 the plan web site.

C. For enrollees who remain in the plan into the subsequent calendar year and who are on a drug as a result of an exception, NHIC will "honor" the exception into the new plan year, according to the original duration approved.

D. NHIC will implement processes defined through the Coverage Determination and Exception Request policy for medical review of non-formulary drug requests, and when appropriate, will switch new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

When a coverage determination request for a non-formulary drug is received, a series of questions are posed that ask if the enrollee has tried any available formulary drugs that treat the same medical condition as the requested non-formulary drug. A list of formulary drugs is provided if responses indicate that formulary drugs have not been tried OR that they were tried, but failed to appropriately treat the enrollee's condition.

When a request for a non-formulary drug is received, our coverage determination process will ensure that the requested drug is being used for a Part D covered use. If an exception is requested, provider must provide sufficient rationale substantiating the exception. We exchange information with the requestor about formulary drugs that treat the same condition to establish whether or not the formulary alternatives available have been tried but were not effective and/or would have adverse effect on the enrollee.

When an adverse decision is made, written notice is sent to the enrollee providing the basis for the denial and includes the formulary alternative drug name(s) along with the enrollee's right to request an appeal if they disagree with the decision. The enrollee's prescriber is also provided a notice of the denial with the same details.

VI. Emergency Fill Procedures

A. Emergency Supplies for LTC Residents. If, at any time, including beyond the first 90 days of membership and after the transition period has expired, a LTC pharmacy requests coverage of a non-formulary or restricted/limited drug subject to prior authorization, step therapy, or quantity limits but does not have the necessary information to process an exception request, NHIC or their delegate will authorize coverage of an emergency fill up to at least a 31-day

supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days or the minimum emergency transition fill allowed) while an exception or prior authorization is requested. This will allow the LTC pharmacy to:

1. Dispense the medication

2. Meet the conditions of participation as required by Medicare
3. Provide time to gather the information necessary to process the exception request

B. Level of Care Changes: NHIC, or its delegate, will provide access to medications for beneficiaries experiencing a level of care change from one treatment setting to another (for example admitted to or discharged from a LTC facility or hospital). Early refill edits will not be used to limit appropriate and necessary access to an enrollee's Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge. Pharmacies may contact NHIC or its delegate to request a review of an early refill edit override.

VII. Cost-Sharing: There may be patient cost sharing for a temporary supply of drugs provided under the transition process. NHIC or its delegate will ensure that temporary supplies of drugs provided under the transition process will

A. Never exceed the statutory maximum copayment amounts for LIS eligible enrollees

B. Base cost-sharing for non-LIS members on one of the approved cost-sharing tiers

1. For formulary drugs (but subject to requirements/limits), the tier will be consistent with the cost-sharing tier that otherwise normally applies to that drug based on the formulary tier assignment on which the drug resides once the utilization management criteria are met.

2. For non-formulary drugs, the tier will be consistent with the cost-sharing that NHIC would charge for non-formulary drugs approved under a formulary coverage exception.

VIII. Implementation

A. NHIC or their delegate will implement soft edits during the claim adjudication process to enable temporary transition fills for Part D eligible drugs. At the point-of-sale, adjudication systems will identify the transition eligible enrollee and the transition eligible non-formulary drugs or drugs subject to requirements/limits (including negative non-formulary or utilization management changes across plan years for affected current enrollees). Soft edits allow claims to process without the need for hard edits and pharmacy overrides at the point-of-sale.

B. Eligibility and Management of Claims. Upon pharmacy submission of a prescription, the Transition Supply adjudication processes operate as follows:

1. Confirmation of beneficiary enrollment in a Part D plan

2. Verification of an active transition window by interrogating the beneficiary's eligibility history

3. Confirmation that the drug submitted qualifies for a transition supply based on the reject messaging about to occur indicating one of four transition eligible categories

    a. Non-formulary

    b. Prior Authorization

    c. Step Therapy

    d. Quantity Limit

4. Confirmation that the date of service falls within the transition window

5. Confirmation of the NHIC allowable transition supply day supply. 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.

    b. 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.

    c. When a claim is submitted with a quantity greater than the overarching plan limits and the day supply submitted exceeds the transition window allowed day supply, 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.

C. If a LTC member 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 allowed.

D. For current enrollees affected across contract years, whose drugs are either no longer on NHIC's formulary or remain on the formulary but are subject to new utilization management restrictions, NHIC, or their delegate, will provide a

meaningful transition process consistent with the transition process required for new enrollees beginning in the new contract year. The member will be eligible for a transition fill if:

1. The enrollee had a history of a paid claim found within the last 365 days of the previous plan year for Protected Class Drugs and 180 days of the previous plan year for non-Protected Class Drugs.

2. The drug is the same as that which experienced a negative formulary status change across contract years.

3. The enrollee is in the same CMS contract ID

4. The history claim did not pay under transition logic for non-protected class drugs

E. NHIC will ensure that it will apply all transition processes to a brand-new prescription for a non-formulary or restricted/limited drug if it cannot make the distinction between a brand-new prescription for a non-formulary or restricted/limited drug and an ongoing prescription for the drug at the point-of-sale.

F. For subsequent fills after the initial transition fill or beyond the transition fill window.

1. If a previous transition supply of the same drug was already dispensed within the same transition window, the process will verify whether a refill is allowable based on the previous day supply already dispensed.

2. If the required full transition supply was found to have already been provided to the enrollee while in their transition window, the process will hard reject the claim and return the claim and return an "IF LEVEL OF CARE CHANGE" 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.

3. If the member is outside of the transition window for a drug that is otherwise transition eligible, the claim will hard reject with appropriate reject codes returned to the pharmacy, including secondary messaging to inform the pharmacy to contact the help desk if a Level of Care change occurred. A manual process will confirm whether or not a level of care change occurred, and if warranted, and a series of override codes will be provided to allow a one-time transition supply to be dispensed.

G. Point-of-sale Processing and Messaging

1. If a claim is approved under temporary fill criteria, it will successfully adjudicate and include messaging at the point of sale indicating that the claim was paid pursuant to temporary transition fill requirements or as an emergency supply and a CMS-approved letter will be sent to the

beneficiary and provider as described this policy. Messaging, as appropriate, will be provide at the time a claim is paid.

2. If the claim is transition eligible for a transition eligible member, but an edit is in place that triggers the hard reject of the claim, 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 the point of sale. The hard reject messaging conditions that may be triggered during adjudication of a transition supply eligible claim are:

    a. Plan Limits Exceeded

    b. If Level of Care Change Call Help Desk

    c. Maximum Daily Dose Exceeded

    d. Refill Too Soon

    e. Med B/D Determination Required

    f. Med D/Non-D Determination required

    g. Short Cycle Fill

    h. Part A versus D Determination required

3. For ineligible enrollees where the claim does not meet transition fill criteria, the claim will be rejected. At the point of sale, the pharmacy will receive appropriate messaging related to the rejection.

4. NHIC or their delegate will only impose utilization management edits during transition to determine Part A or B versus Part D coverage, prevent coverage of non-Part D drugs, and promote safe utilization of a Part D drugs (e.g., quantity limits based on FDA maximum recommended dose, early refill edits) during transition at point-of-sale. Other step therapy and prior authorization edits will be resolved at point-of-sale. In the case of Part A, or B versus D overlap drugs or non-Part D drugs, a coverage determination is required prior to payment. Plan oversight is required to assure prescriber's response to coverage review requests for enrollee access to needed medications. <u>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</u>

provider – request prior authorization. Call for review if not Hospice/Unrelated."

IX. NHIC will make the transition policy available to enrollees via a link from the Medicare Prescription Drug Plan Finder to the NHIC web site and will include pre- and post- enrollment marketing materials as directed by CMS.

X. Logging, Tracking and Reporting: NHIC, or its delegate, will ensure that its transition process is administered according to CMS requirements, and will provide CMS with the necessary reporting related to transition as required

A. Reject reports will be reviewed by NHIC and/or their delegate for program oversight to ensure that current and new beneficiary transition processes are working appropriately, which may result in direct pharmacy and/or member outreach to achieve a paid supply and ensure enrollee access to drugs.

B. NHIC will process trial claims and document results to test the PBM's transition process for both formulary accuracy and implementation process appropriateness

C. Should ad hoc reporting be required by CMS, NHIC or its delegate will develop reporting as required

XI. Emergency/Disaster Fill Procedure Part D Access in an Emergency Area: To guarantee immediate refills on Part D Medications, NHIC, or its delegate:

A. Will remove "refill too soon" edits for the period of the emergency declaration

B. Will allow the enrollee to obtain the maximum extended day supply if available

C. Will guarantee out-of-network benefits for those beneficiaries who are displaced and cannot reasonably access a network pharmacy

XII. Role of the Pharmacy and Therapeutics Committee

A. Reviews and approves Medicare Transition Policy as outlined in this document on an annual basis.

B. Per CMS guidance, P&T involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are not on the plan's formulary.

C. Per CMS guidance, P&T involvement will help ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs that are on the formulary but are subject to Prior Authorization, Step Therapy, and Quantity Limits as part of a plan's utilization management requirements. This is accomplished via P&T review and approval of the appropriate policies and procedures.

Regulatory Citations:

- 42 CFR 423.120(b)(3) Transition Process Medicare Prescription Drug Benefit Manual
- Chapter 5, Section 50.12: Pharmacy Access During a federal Disaster or Other Public Health Emergency Declaration
- Chapter 6, Section 30.4 Transition

Related Policies: None

Related Documents:

None

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