Policy & Procedure

POLICY

Health Choice Generations (HCG) provides a Part D drug transition process in order to prevent enrollee medication coverage gaps. HCG's transition process is consistent with 42 CFR §423.120(b)(3) and describes how, for enrollees whose current drug therapies may not be included in the HCG plan year formulary, HCG will effectuate a meaningful transition for: (1) new enrollees into HCG at the start of a contract year; (2) newly eligible Medicare beneficiaries from other coverage ; (3) enrollees who switch from one Part D plan to HCG 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;

HCG's transition process applies to non-formulary drugs, namely; (1) Part D drugs that are not on the HCG formulary; and (2) drugs previously approved for coverage under an exception once the exception expires; and (3) Part D Drugs that are on the HCG formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose.

HCG provides a temporary supply of a non-formulary Part D drug or formulary drug requiring prior authorization (PA) or step therapy (ST) to ensure that enrollees have needed continuity of drug therapy and have sufficient time to work with their health care provider(s) to switch to a therapeutically appropriate formulary alternative or to request a formulary exception on the grounds of medical necessity.

The policy will have be reviewed and approved by HCG's delegated P&T Committee, and Director of Pharmacy and HCG Compliance Department on an annual basis.

DEFINITIONS

Emergency Fill: After the initial new-enrollee transition period and initial 90 days formulary change across contract year period, LTC facility residents who are ordered non-formulary, PA, ST drugs, must receive their medications as ordered without delay. Therefore, HCG will cover an emergency supply of these drugs for LTC facility residents as part of their transition process. These emergency supplies will be for at least 31 days of medication, unless the prescription is written by a prescriber for less than 31 days, in this case allow multiple fills up to 31 days' supply.

Formulary: HCG's formulary contains brand-name and generic products. The formulary is created under the direction of HCG's designated Pharmacy and Therapeutics Committee (P&T Committee).

Formulary Changes Across Contract Years: Includes drugs that will become Non-Formulary (no longer covered on the formulary), or drugs that remain on the formulary but have new PA or ST restriction added from one contract year to another (negative change).

Level-of-Care Change: When an enrollee is changing from one treatment setting to another. Examples include, but are not limited to: (1) beneficiaries who enter LTC facilities from hospitals; (2) beneficiaries who are discharged from a hospital to a home; (3) beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary; (4) beneficiaries who give up hospice status to revert to standard Medicare Part A and B benefits; (5) beneficiaries who end an LTC facility stay and return to the community; and (6) beneficiaries who are discharged from psychiatric hospitals with drug regimens that are highly individualized.

Long-Term Care (LTC) Facility: A skilled nursing facility as defined in section 1819(a) of the Social Security Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Social Security Act.

Medicare Part D Excluded Drugs: Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2) or (d)(3) of the Social Security Act, except for smoking cessation agents.

Prior Authorization (PA), Step Therapy (ST), Quantity Limits (QL): Two-letter codes used to designate utilization management tools.

Transition Notice: A written notice mailed to the enrollee following receipt of a temporary fill during the transition period. The notice is in accordance with CMS guidance and contains the following information: (1) an explanation of the temporary transition supply the enrollee has received during the transition period; (2) instructions for working with HCG and the enrollee’s prescriber to identify appropriate therapeutic alternatives on the HCG formulary or exception request forms (available to enrollee) for formulary drugs that need a prior authorization or step therapy; (3) an explanation of the enrollee’s right to request an exception; and (4) a description of the procedure for requesting an exception.

Utilization Management (UM): Tools used to ensure appropriate use of formulary medications such as prior authorization (PA), step therapy (ST), and quantity limits (QL).

PROCEDURES

A. Submission and Communication of Policy

1. HCG will submit the Transition Policy to CMS for review and approval.
2. HCG will make the Transition Policy available via link from Medicare Prescription Drug Plan Finder to HCG web site and include in pre-and post-enrollment marketing materials as directed by CMS.

B. Transition for Non-Formulary Drugs and Drugs with UM controls

1. HCG, or its designee, has system capabilities (via point-of-service electronic transactions) that allow a temporary supply of non-formulary Part D drugs or Part D formulary drugs that require a UM edit in order to accommodate the immediate needs of an enrollee, and allow the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or complete an exception request.

2. HCG, or its designee, will apply the following UM edits during transition at point-of-sale:
   a. Edits to determine Part A or B versus Part D coverage
   b. Edits to prevent coverage of non-Part D drugs
   c. Edits to promote safe utilization of a Part D drug
   d. Step therapy and prior authorization edits will also be resolved at point-of-sale.

3. HCG has established medical review and coverage determination processes to evaluate the medical necessity of non-formulary drug requests and to provide authorizations or therapeutic formulary alternatives when medical necessity is not affirmed.

4. Enrollees and physicians can obtain forms to arrange for prior authorization (PA) of non-formulary drugs through a variety of means, including mail, fax, email, and HCG's website.

5. For current enrollees whose drugs are no longer on the formulary, or remain on the formulary but with new prior utilization or step therapy restrictions applied, HCG or its designee 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.

C. New Enrollee Transition

1. Retail Setting

    a. HCG will provide for at least a one-time, temporary 30-day fill, unless, the enrollee presents with a prescription written for less than 30 days, in which case HCG, or its designee, will allow multiple fills to provide up to a total of 30 days of medication.
    b. The fill(s) may occur anytime during the first 90 days of a beneficiary's enrollment in HCG, beginning on the enrollee's effective date of coverage.
2. Long-Term Care (LTC) Setting
    a. HCG will provide for a 91 - 98-day fill consistent with the applicable dispensing increment in the long-term care setting, with refills provided, if needed, during the first 90 days of a beneficiary's enrollment in a HCG, beginning on the enrollee's effective date of coverage.
    b. After the transition period has expired, the transition policy provides for a 31-day emergency supply of Part D covered non-formulary medications, including Part D covered drugs that are on the formulary that would otherwise require prior authorization or step therapy under the utilization management rules (unless the enrollee presents with a prescription written for less than 31 days), while an exception or prior authorization is requested or when it has been identified that the enrollee’s exception request or appeal has not been completed by the end of the transition period.
    c. For enrollees being admitted to or discharged from a LTC facility, early refill edits will not be 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.
    d. LTC enrollees are identified based on the patient residence code submitted on the claim. This indicator permits the total day supply of the transition fill allowed for a total of 98 days.

3. HCG 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 an enrollee’s 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).
    a. Extensions need to be initiated by the beneficiary, the beneficiary’s representative, prescriber, or pharmacy. Requests can be made in writing, by email or fax, or telephonically.

D. Existing (Current) Enrollee Transition

1. Long-Term Care (LTC) Setting

a. HCG will provide for a 91 to 98-day fill consistent with dispensing increment requirements,(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 HCG, beginning on the enrollee's effective date of coverage.
b. After the new enrollee transition period has expired, HCG provides for a 31-day emergency supply of non-formulary Part D drugs, including Part D covered drugs that are on the formulary that would otherwise require prior authorization or step therapy under the utilization management rules (unless the enrollee presents with a prescription written for less than 31 days), while an exception or prior authorization is requested or when it has been identified that the enrollee's exception request or appeal has not been completed by the end of the transition period.
c. For enrollees being admitted to or discharged from an 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.
d. In the LTC setting, beneficiaries will be permitted to have a full outpatient supply available under Part D to continue therapy once their limited Part A supply is exhausted.

2. Level-of-Care Changes
    a. HCG provides transition fills for enrollees who experience a transition characterized as a level-of-care change from one treatment setting to another. Examples of level-of-care changes include:
        i. Enrollees who are discharged from a hospital to a home setting (i.e., assisted living, LTC, or private home) accompanied by a list of medications that may not always consider the HCG formulary due to the short-term nature of the hospital visit
        ii. Enrollees who end their skilled nursing facility Medicare Part A stay and who need to revert to their Part D plan formulary
        iii. Enrollees who give up hospice status to revert to standard Medicare Part A and B and Part D benefits
        iv. Enrollees who end an LTC facility stay and return to the community
        v. Enrollees who are discharged from psychiatric hospitals with drug regimens that are highly individualized

    b. HCG considers these unplanned transitions and applies the transition fill process as required. HCG understands that the enrollee is entitled to a full Part D outpatient supply in order to continue therapy.

    c. HCG ensures that enrollees are able to receive their outpatient Part D prescriptions in advance of discharge from a Part A stay through this transition process.

    d. One-Time Fills for Unplanned Transitions from Hospital, LTC, SNF, or Hospice

i. HCG's designee has level-of-care change automated programming that identifies if the member has a change in patient residence code based on the most recent claim. If a change is identified, the system is configured to automatically override the following edits: Refill-too-soon (RTS), Duplicate prescription, Duplicate therapy, Non-formulary, Prior authorization (excluding B vs. D prior authorizations), Step therapy, and Quantity limits.

ii. If the member didn't have a change identified by a change in patient residence code, the pharmacist should call the HCG call center to notify them of the Level-of-Care Change in order to have an authorization placed in the system allowing the claim to pay.

- The authorization will address the above edits, resulting in a paid claim.
- Authorizations will be entered as one-time authorizations. If the member has subsequent Level-of-Care Changes, additional one-time authorizations will be entered to ensure there are no gaps in therapy.

3. HCG 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 an enrollee's 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).
   a. Extensions need to be initiated by the beneficiary, the beneficiary's representative, prescriber, or pharmacy. Requests can be made in writing, by email or fax, or telephonically.

4. Formulary Changes Across Contract Year

   a. For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, HCG will effectuate a meaningful transition by: (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.

      i. A transitional fill will be provided for current beneficiaries who utilized the drug during the past 180 days.
      ii. A temporary supply of the drug (where not medically contraindicated) and an enrollee transition notice, that explains that the enrollee needs to either switch to a drug on the sponsor's formulary or get an exception to continue taking the requested drug, will be provided to the enrollee.

   b. HCG provides for a transition fill for current enrollees within the first 90 days of a new plan year.

c. HCG will extend (carry over) 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. The transition period would not exceed a total of 90 days.

E. Transition Fill Rules

1. HCG ensures that cost-sharing for a temporary supply of drugs provided under its transition process, subject to the following guidelines:

   a. Cost sharing for transition supplies for low-income subsidy (LIS) eligible enrollees never exceeds the statutory maximum copayment amounts
   b. For non- LIS eligible enrollees, charges for cost-sharing for non-formulary drugs is based on one of its approved cost-sharing tiers and is consistent with cost-sharing that is charged for non-formulary drugs approved under a coverage exception.
   c. For non-LIS enrollees, cost sharing for formulary drugs with UM waived for transition supply is based on the applicable formulary tier if the UM criteria are met.

2. HCG ensures 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.

3. HCG ensures 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.

4. HCG ensures that enrollees who receive a transition supply of a PA or ST (formulary) drug in the Six Classes of Clinical Concern will automatically be grandfathered to continue taking that medication throughout their benefit.

   a. Enrollees will not be considered “new starts” and will not need to go through the coverage determination and exception process in order to continue on their medication.
   b. Enrollees will not be sent a transition letter since they will be able to continue on their therapy without interruption.

F. Transition Notifications

1. HCG, or its designee, will send written notice to both the enrollee and the prescriber via U.S. first class mail within three business days of adjudication of a temporary transition fill. The notice will include:

   a. Explanation of the temporary nature of the transition supply an enrollee has received
   b. 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
   c. Explanation of the enrollee's right to request a formulary exception

d. Description of procedures for requesting a formulary exception

2. For long-term care residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less, consistent with the requirements of 42 CFR 423.154(a)(1)(i),the written notice will be provided within 3 business days after adjudication of the first temporary fill.

3. HCG uses the CMS model Transition Notice via the file-and-use process. (See attachment 1 and 2.)

a. One transition letter is generated per claim, so if the drug has exceeded both prior authorization and quantity limit restrictions, one letter will include both reasons.
b. If a member receives multiple transition fills of different drugs on the same day, a letter will be generated for each drug.
c. Transition letters are available in English and Spanish.

4. HCG, or its designee, makes reasonable efforts to contact prescribers of affected enrollees who receive a transition notice via a prescriber transition notice. (see attachment 3)

5. When a transition supply claim is paid through the system, pharmacies will be notified via an electronic message informing them that the fill was part of a transition supply. If the claim encounters a valid transitional reject (e.g. Part B vs Part D, Safety edit, Part D exclude), a message is returned to the pharmacy to indicate the reason for the rejection.

   a. NCPDP-approved message codes are used in the POS pharmacy response.
   b. Messaging verbiage is provided and referenced to access the client's exception request from: "TRANSITION-PA RQD <PA call 1-800-XXX-XXXX> "
   c. Once the transition period has ended, the system will reject those claims for which the products are non-formulary or exceed plan limitations.

6. At least annually, HCG or its designee's pharmacy network will be reminded, via fax blast from the Provider Relations Department, of the clarification codes to submit for transition supply enrollee situations.

This policy will be reviewed on an annual basis.