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LINE OF BUSINESS

This document applies to the following line(s) of business:

Medicare ALL

DEFINITIONS

None

POLICY

In accordance with CMS guidance, Scott & White Health Plan (SWHP) has a transition process to allow enrollees whose current drug therapies may not be included on the SWHP Medicare Part D formulary(s) to continue drug therapy while transitioning onto the SWHP Medicare Part D prescription plans.

Transition includes (1) transition of new enrollees into a Medicare Part D plan; (2) transition of newly eligible enrollees into a Medicare Part D plan from other coverage; (3) transition of enrollees from one plan to another after the start of a plan year (i.e., after January 1); (4) movement of enrollees in or out of an LTC facility; or (5) current enrollees in a Medicare Part D plan affected by formulary changes from one plan year to the next.

PROCEDURE

TRANSITION SUPPLY FOR NON-FORMULARY DRUGS

1. SWHP has system capabilities that allow a temporary supply of non-formulary Part D drugs in order to accommodate immediate needs of an enrollee, as well as to allow the plan and/or 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.
2. SWHP's Transition Process policy applies to non-formulary drugs, meaning both:
    a. Part D drugs that are not on formulary

   b. Part D drugs that are on formulary but require prior authorization (PA) or step therapy (ST), or that have an approved quantity limit (QL) lower than the beneficiary's current dose, under the utilization management (UM) rules.
3. There are policies and procedures in place 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. A member must meet appropriate medical necessity and coverage criteria before a non-formulary exception request will be approved. Lack of medical necessity may result in member switching to therapeutically appropriate formulary alternatives through the non-formulary exception process as described in the Medicare Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeals.
   a. To determine medical necessity, there is verification through the prescriber's supporting statement and/or standards, documented in clinical guidelines adopted by SWHP, that the requested prescription drug is medically necessary to treat the member's disease or medical condition and meets one of the following three criteria:
      i. Other formulary or covered drugs on any tier of the formulary would not be as effective for the member as the non-formulary drugs and/or the other drugs would have adverse effects; or
      ii. No other formulary or covered drugs on any tier of the formulary would be as effective for the member as the non-formulary drugs and/or the other drugs would have adverse effects; or
      iii. The formulary or covered alternative has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the member. Enrollees and physicians may obtain forms to arrange for an exception of non-formulary drugs through a variety of means, including mail, fax, email, and the SWHP website. Although these forms are not required, they are helpful for the evaluation of the requests.

TRANSITION SUPPLY FOR DRUGS WITH UM CONTROLS

1. The Transition Process policy also applies to Part D drugs that are the formulary but require PA, ST, or QL under the UM rules.
   a. The following UM edits are applied during transition at point-of-service (POS):
      i. Edits to determine Part A or B vs. Part D coverage
      ii. Edits to prevent coverage of non-Part D drugs
      iii. Edits to promote safe utilization of a Part D drug

2. There is 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 (Refer to "Transition Supply for Non-Formulary Drugs").

TRANSITION FOR NEWLY IMPLEMENTED UM CONTROLS

1. For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, a meaningful transition is effectuated by providing transition procedures consistent with the transition process required for new enrollees at the start of the new contract year.

RETAIL SETTING - TEMPORARY FILL AMOUNT

1. In the retail setting, the Transition Process policy provides for at least a one-time, temporary month's supply, unless the enrollee presents with a prescription written for less than a month's supply, in which case multiple fills are allowed to provide a total of a month's supply medication. Appropriate transition fills are allowed for drugs manufactured in "unbreakable packages."
2. This may occur anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.
3. If applicable, a transition fill is provided for current enrollees within the first 90 days of the plan year under "Formulary Change across Contract Year" transition rules.

COST-SHARING ON TEMPORARY FILLS

1. Cost-sharing is applied for a temporary supply of drugs provided under the transition process, subject to the following guidelines:
    a. Cost-sharing for transition supplies for LIS-eligible enrollees never exceeds statutory maximum copayment amounts.
    b. For non-LIS enrollees, charges for cost-sharing for non-formulary drugs is based on one of the approved drug cost-sharing tiers, and this cost-sharing 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 had the UM not been waived for transition.

TRANSITION FOR LTC SETTING

1. SWHP ensures that in the LTC setting:
    a. The Transition Process policy provides for a month's supply fill consistent with dispensing increment requirements, 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.
    b. After the transition period has expired, the Transition Process policy provides for a 31-day emergency supply of non-formulary Part D drugs consistent with dispensing requirements while an exception or PA is requested.
    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. LTC enrollees are identified based on patient residence code submitted on claim(s). This indicator permits a refill of a month's supply of transition medication.

LEVEL-OF-CARE CHANGES

1. Transition fills are provided for enrollees who experience a transition characterized as a level-of-care change from one treatment setting to another.
2. Examples of level-of-care changes where a transition may apply include:
    a. 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 formulary of the enrollee's plan due to the short-term nature of the hospital visit
    b. Enrollees who end their SNF Medicare Part A stay (where payments include all pharmacy charges) and who need to revert to their Part D plan formulary
    c. Enrollees who give up hospice status to revert to standard Medicare Part A and B benefits
    d. Enrollees who end an LTC facility stay and return to the community

   e. Enrollees who are discharged from psychiatric hospitals with drug regimens that are highly individualized
3. These are considered unplanned transitions and applies the transition fill process as required.
4. While Part A provides reimbursement for “a limited supply” to facilitate enrollee discharge, the enrollee is entitled to a full outpatient supply in order to continue therapy once this limited supply is exhausted. This is particularly true for enrollees using a mail-order pharmacy or home infusion therapy, or for those residing in rural areas where obtaining a continuing supply of drugs may involve certain delays.
5. Enrollees are able to receive their outpatient Part D prescriptions in advance of discharge from a Part A stay through this transition process.

ONE-TIME FILLS FOR UNPLANNED TRANSITION FROM HOSPITAL, LTC, SNF, OR HOSPICE

1. For an enrollee leaving a hospital, SNF, or hospice setting (where prescriptions are covered under Medicare Part A or Part B), the discharge list of prescription orders may contain medications that are either non-formulary or subject to UM edits.
2. The level-of-care change automated programming identifies whether or not the member has a change in patient residence code based on most recent claim.
3. If a level-of-care change is identified, the system is configured to automatically override the following edits on Part D-covered drugs to allow the claim to pay:
   a. Refill-too-Soon
   b. Duplicate prescription
   c. Duplicate therapy
   d. Non-formulary
   e. Prior authorization (excluding Part B vs. Part D or Part D vs. Part D-excluded drugs)
   f. Step therapy
   g. Quantity limits
4. If the member did not have a change identified by a change in patient residence code, in order to ensure that the enrollee does not have a gap in therapy, the pharmacist should call the pharmacy 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.
5. This authorization is to address the above edits, resulting in a paid claim.
6. These authorizations are to be entered as one-time authorizations; however, if the member has subsequent level-of-care changes, additional one-time authorizations are to be entered to ensure there are no gaps in therapy.
7. If the rejection is related to a clinical reason (i.e., non-formulary, PA, ST, QL), the clinical call center is also notified to begin coverage determination and exception process with the prescriber.
8. Enrollees are provided with appropriate written transition letter notification regarding their transition supply for any of the reasons indicated in the CMS model transition notice. This notice includes an explanation of the temporary nature of the transition supply, along with instructions for working with the plan and the enrollee’s prescriber to determine an appropriate therapeutic formulary alternative.
9. Additionally, the letter template provides an explanation on the enrollee’s right to request a formulary exception with procedures on how to pursue that option.
10. One transition letter is generated per claim, even when multiple UM restrictions have been waived. For example, if the drug has exceeded both PA and QL restrictions, one letter is sent and includes both reasons.
11. If a member receives multiple transition fills of different drugs on the same day, a letter is to be generated for each drug.
12. At least annually, the pharmacy network is to be reminded of clarification codes to submit for these situations via fax blast.

QUANTITY LIMITS, REFILL-TOO-SOON, AND SAFETY EDITS

1. The Transition Process policy provides for refills of transition prescriptions dispensed for less than written amount due to QLs for safety purposes or drug utilization edits that are based on approved product labeling.
    a. Only certain drug UM edits are applied during a beneficiary's transition period at POS.
    b. Drug utilization management edits that are appropriate during this transition period include: edits to help determine Part A or B vs. Part D coverage; edits to prevent coverage of non-Part D drugs (i.e., excluded drugs); or edits to promote safe utilization of Part D drugs (i.e., MADD edits based on FDA maximum recommended doses, early refill edits); or edits to maximize appropriate dose.
2. Edit are applied to certain non-six clinical class drugs, MADD edits, B vs. D administrative PA edits, and early refill edits during transition. Resolution of edits is made by the dispensing pharmacist at POS by either: (1) resubmitting claim with revised/corrected information, or (2) calling the Member Services Department/Pharmacy Help Desk.
3. Edits applied during transition are managed and resolved through POS and review activity.
4. If any non-formulary, PA, ST, or QL edit is overridden at POS for transition purposes only, but not permanently, SWHP notifies the beneficiary so that s/he can begin the exception process, if necessary. Notification occurs via U.S. first-class mail to the enrollee within three (3) business days of adjudication of a temporary fill. Notification specifics are outlined under "Transition Notification" section.
5. Additional ST-type PA or PA edits are implemented during transition if such edits can be resolved at POS.
6. All non-formulary, PA, and ST edits are subject to exception request and appeal. Beneficiaries are made aware of any edits that result in a prescription being filled differently than originally written, as well as their right to request an exception.
7. Such exception requests are expeditiously processed so that beneficiaries do not experience unintended interruptions in medically necessary Part D drug therapies and/or inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.
    a. All non-formulary, PA, ST, or QL edits (not including Part B vs. Part D or Part D vs. Part D-excluded prior authorizations, edits to reject non-part D drugs, QLs for safety reasons, and early refill edits) are overridden during the transition period to allow multiple fills up to the overall transition days' supply limit. Multiple refills of transition supply may therefore be obtained up to the maximum allowable days' supply of a transition supply.
    b. Enrollees must be allowed to refill a transition supply of a non-formulary Part D drug if the prescription is dispensed for less than the written amount due to QLs for safety purposes or drug utilization edits that are based on approved product labeling.
    c. All non-formulary, PA, ST, or QL edits are to be resolved at POS adjudication. No "hard edits" are utilized in order to manage transition supplies. Since UM edits (except Part B vs. Part D or Part D vs. Part D-excluded prior authorizations, edits to reject non-part D drugs, QLs for safety reasons, and early refill edits)) are overridden to allow a transition fill during the first 90 days of enrollment, there is no need for retail, home infusion, safety-net, or ITU pharmacists to enter an override. These claims pay without any additional input from the submitting pharmacist, and the enrollee, therefore, never leaves the pharmacy without a transition supply.

MESSAGING

1. During the transition period, the claims system allows a transitional fill for all products identified as transition-eligible. The coding and claims processing system allows temporary supplies of non-formulary Part D drugs (including Part D drugs that are on the formulary but require PA, ST, QL-type PA under UM rules). The claims processing system has an automated configuration that determines whether or not the criteria for a transition supply is met. Claims are processed at POS and do not require additional action from the pharmacist, unless an allowable edit is in place. This accommodates the immediate needs of an enrollee, as well as allowing the plan and/or enrollee sufficient time to work with 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.
    a. If a transition fill is effectuated, the dispensing pharmacy receives:
        i. A free text message in the pharmacy response identifying this as a transition fill and other information related to authorization processing as needed.
        ii. NCPDP-approved message codes in the pharmacy response. The pharmacy only receives NCPDP reject codes relative to transition and is dependent on pharmacy's software to apply appropriate message.
        iii. When a transition supply claim is paid through the system, pharmacies are notified via an electronic message informing them that fill was part of a transition supply. If the claim encounters a valid transitional reject, a message is returned to the pharmacy to indicate reason for rejection.
    b. Once the transition period has ended, the system rejects those claims for which products are non-formulary, need PA, or exceed plan limitations.

TRANSACTIONAL CODING IMPLEMENTATION

Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, there will be implementation of either:

1. Appropriate system changes to achieve goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim, or
2. Alternative approaches that achieve goals intended in the messaging guidance

DETERMINING ONGOING THERAPY

1. Transition processes apply to a brand new prescription for a non-formulary drug if unable to make the distinction between a brand new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug at POS.
2. For enrollees who remain in the same plan and are on a drug as a result of an exception that was granted in the prior year which continues to be active past the current contract year (e.g., the authorization extends into the new contract year), such exceptions will be allowed in the new contract year.
3. Protected Class Drugs
    a. Enrollees who receive a transition supply of a PA or ST (formulary) drug in the "Six Classes of Clinical Concern" are automatically grandfathered to continue taking that medication throughout the benefit year.
    b. They are not to be considered "new starts" and do not need to go through coverage determination and exception process in order to continue on medication.

c. These members are not to be sent a transition letter since they will continue on their therapy without interruption.

TRANSITION NOTIFICATION

1. Transition supplies are identified by the adjudication system based on specific indicators on the claim.
2. For transition claims, “Formulary Change across Contract Year” and “Level-of-Care Emergency Fill” transition claims, each claim is stamped with a transition claim indicator.
3. These indicators are used to define the type of transition and the reason for the transition, as defined in the CMS transition letter template (i.e., non-formulary, PA, ST, etc.).
4. If a temporary fill is provided for a Part D drug under applicable transition process, an appropriate written notice regarding the transition process is mailed within three (3) business days of the temporary fill submitted by provider.
5. Written notice is sent to both the enrollee and the prescriber via U.S. first class mail within three (3) business days of adjudication of a temporary fill. The notice must include:
    a. Explanation of temporary nature of transition supply an enrollee has received
    b. Instructions for working with SWHP and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the formulary
    c. Explanation of enrollee's right to request a formulary exception
    d. Description of procedures for requesting a formulary exception
6. For LTC 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), written notice is to be provided within three (3) business days after adjudication of first temporary fill.
7. SWHP utilizes the CMS model transition letter for transition notification.

AVAILABILITY OF FORMS FOR PAs AND FORMULARY EXCEPTIONS

1. Upon request, PA or exception request forms are made available to both enrollees and prescribing physicians via a variety of mechanisms, including mail, fax, email, and on the SWHP website. The forms, however, are not required; they are provided for convenience.

AVAILABILITY OF THE TRANSITION POLICY TO ENROLLEES

1. This policy is reviewed and approved by the P&T Committee.
2. The Transition Policy is provided via the SWHP website and in pre- and post-enrollment marketing materials.
3. CMS guidance is monitored and updated or revisions are made to the current policy as needed.

EXTENSION OF TRANSITION ON CASE-BY-CASE BASIS

1. Arrangements are made 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).
2. Extensions need to be initiated by the beneficiary, beneficiary’s authorized representative, prescriber, or pharmacy. Requests may be made in writing, telephonically, or by email or fax.

TRANSITION ACROSS CONTRACT YEARS

1. For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, SWHP will effectuate a meaningful transition by providing a transition process at the start of the new contract year for current enrollees consistent with the transition process required for new enrollees. In order to prevent coverage gaps, this option provides a temporary supply of the requested prescription drug (where not medically contraindicated) and provide enrollees with notice that they must either switch to a drug on the formulary or get an exception to continue taking the requested drug.
2. SWHP extends its Transition Process 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.
3. When such exceptions have been approved, the enrollee is able to continue on the medication through the end of that contract year (ensuring payment is authorized prior to January 1), and through the next contract year in accordance with the "Coverage Determinations" policy, and based on the CMS-approved coverage duration defined in the PA criteria.
4. If the enrollee, enrollee's authorized representative, or physician has submitted a coverage determination and exception request, and the decision is still pending on the last day of the contract year, an override for a one-time temporary month's supply is to be entered to ensure there is no coverage gap while proceeding through the exception process. Even though the one-time authorization has been entered, the clinical call center team still turns around the exception request within the CMS-required time frames.
5. If the enrollee, an authorized representative, or prescribing physician has not requested an exception prior to the end of the contract year, the enrollee, their authorized representative, or the prescribing physician must still request a coverage determination exception review as expeditiously as possible.
6. If the enrollee has not successfully transitioned to a formulary alternative by January 1, SWHP provides a transition supply beginning January 1, consistent with the process for new enrollee transitions, by programming the negative formulary changes across contract years (drugs that have UM added or have become non-formulary) to allow the additional transitional fill for current beneficiaries who utilized the drug during the past at least 120 days.

P&T COMMITTEE / MEDICAL POLICY GROUP RESPONSIBILITIES

1. The P&T Committee/Medical Policy Group review provides recommendations regarding procedures used for medical review of drugs requiring PA, ST, QL, or non-formulary drug requests.
2. P&T Committee/Medical Policy Group involvement ensures that transition decisions appropriately address situations involving:
    a. Enrollees stabilized on drugs that are not on formulary and that are known to have risks associated with any changes in the prescribed regimen.
3. Enrollees stabilized on drugs that are on formulary but require PA, ST, or QL-type PA under the UM requirements and that are known to have risks associated with any changes in the prescribed regimen.
4. The P&T Committee reviews this transition policy at least annually to ensure that transition decisions appropriately address situations involving enrollees stabilized on drugs, either non-formulary drugs or formulary drugs, that require PA, ST, or QL, and which may have risks associated with a change in the prescribed regimen.

ATTACHMENTS

None

RELATED DOCUMENTS

None.

REFERENCES

1. CMS Prescription Drug Plan Manual - Chapter 6 – Part D Drugs and Formulary Requirements
2. 42 CFR 423.120(b)(3)