

Prescription Drug Transition Process

Purpose

To define the process that supports a member's transition into prescription drug plans and to provide a temporary supply of non-formulary drugs. Members and situations affected by this transitional fills policy:

- a. The transition of new members into prescription drug plans following the annual coordinated election period;
- b. The transition of newly eligible Medicare beneficiaries from other coverage;
- c. Enrollees who switch from one plan to another after the start of the contract year;
- d. Current enrollees affected by negative formulary changes across contract years;
- e. Enrollees residing in LTC facilities;
- f. Expediting transitions to formulary drugs for members who change treatment settings due to changes in level of care.

Navitus Health solutions (NHS) has established a transition process for Part D beneficiaries to be consistent with the CMS Guidelines.

Policy

Navitus Health Solutions (NHS), as a delegated downstream entity of our contracted plan sponsors, will use the process developed to abide by the Centers for Medicare & Medicaid Services (CMS) guidelines. Navitus' adjudication system logic automatically identifies claims eligible for a temporary supply of non-formulary Part D drugs (including Part D drugs that are on the Part D formulary, but require prior authorization, step therapy or that have an approved QL lower than the beneficiary's current dose under our utilization management rules) and effectuates payment in order to accommodate the immediate needs of an enrollee. For these claims, a transition notice will be sent to the enrollee and the prescriber. This allows 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. This will promote continuity of care and avoid interruptions in drug therapy.

In certain circumstances, Navitus will extend the transition period and provide the necessary drugs if the enrollee's exception request or appeal has not been processed by the end of the minimum transition period.

In addition to providing primary transition administration for Navitus' Part D plan, Navitus is contracted to facilitate beneficiary phone calls for secondary support of a contracted Part D Plan Sponsor. For EGWP customers, Navitus is the primary point of contact.

Navitus incorporated the transition policy into its formal training and processes.



Transition Implementation Statement

Navitus Health Solutions (NHS) will ensure beneficiaries in their transition period are provided temporary fills for non-formulary drug(s) (including Part D drugs that are on the formulary but require prior authorization, require step therapy, or that have an approved QL lower than the beneficiary's current dose) during the first 90 days of their benefit period. In certain instances, Navitus applies drug utilization management edits during the beneficiary's transition period. These edits are limited to:

- 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 formulary drugs being dispensed for an indication that is not medically accepted); and
- Utilization Review Edits to promote safe utilization of a Part D drug (i.e. member-level opioid claim edit, quantity limits based on FDA maximum recommended daily dose, early refill edits)

While Navitus may implement step therapy, prior authorization or quantity limits edits during transition, we only do so if the edits are resolved at the point of sale. Navitus describes the edits, adjudication processes, pharmacy notification processes in section 8 of this policy.

Our adjudication system is set up so that all non-formulary Part D drugs and all drugs requiring utilization management edits will process automatically for a member in their transition period. To accomplish this, the Navitus adjudication system will apply the edits noted above and in Section 8b, and if the claim doesn't meet one of these restrictions, there are no further transition medication edits to be resolved at the point of sale and the claim will process automatically. To meet CMS' intent for messaging to pharmacies for transition fill notices at point of sale, in accordance to Chapter 6 Sec. 30.4.10 and Chapter 14 Sec. 50.5, Navitus has implemented enhanced transition fill messaging functionality in the claims adjudication system. This provides messaging to the submitting pharmacy with notification of a transition fill for the beneficiary.

Regulatory/Requirement References

Med D

- CMS Med D Prescription Drug Benefit Manual – Chapter 6, Section 30.4
- HPMS Memo
- Other

MMP

- State Regulatory Guidance
- CMS

Definitions:

ANOC	CMS abbreviation for Annual Notice of Change
CMS	Center for Medicare and Medicaid Services; government agency charged with overseeing the Medicare Part D program
NHS Pharmacy and Therapeutics (P&T) Committee	An advisory committee, meeting quarterly, that is responsible for reviewing clinical information regarding medications and making formulary recommendations to NHS. The P&T Committee is comprised of primary-care and specialty physicians, as well as pharmacists. The members of the P&T Committee are not NHS employees.
PBM	Pharmacy Benefits Manager
Plan Sponsor	Contracted Medicare health plan that sponsors Part C and Part D benefits

Area(s) of Responsibility

Department: Formulary Services

Department: Medicare D Operations

Department: Medicare D Clinical Programs

High Level Procedures

1. Members and situations affected by this transitional fills policy in which Navitus and/or the Plan Sponsor will apply a transition process consistent with 42 CFR §423.120(b)(3) as detailed in the policy below:
 - A. The transition of new enrollees into prescription drug plans following the annual coordinated election period;
 - B. The transition of newly eligible Medicare beneficiaries from other coverage;
 - C. Enrollees who switch from one plan to another after the start of the contract year;
 - D. Current members affected by negative formulary changes across contract years;
 - E. Enrollees residing in LTC facilities;
 - F. Expediting transitions to formulary drugs for members who change treatment settings due to changes in level of care.
2. General Guidelines
 - A. Navitus' transition process is applicable to:
 - I. Part D drugs that are not on Part D/Plan Sponsor's Part D formulary
 - II. Part D drugs that are on Part D/Plan Sponsor's Part D formulary but require prior authorization, exceed quantity limits or require step therapy under Navitus'/Plan Sponsors' utilization management rules.
 - B. Navitus ensures that we provide our members, who have used a transition benefit, with the appropriate assistance and information necessary to enable them to better understand the purpose of the transition supply. This includes:
 - I. Analyzing claims data to determine which members require information about their transition supply.
 - II. Contacting those members to ensure they have the necessary information to enable them to switch to a formulary product or, as an alternative, to pursue necessary prior authorizations or formulary exceptions.
 - i. Exception requests are processed consistent with CMS requirements outlined in Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance for medical review of non-formulary drug requests and to determine whether to approve or deny the request based on the exception criteria established.

- ii. Should an exception request be denied, the beneficiary and prescriber receive a notice that provides information regarding appeal rights and the denial decision, including any specific formulary criteria and/or therapeutically appropriate formulary alternatives that must be satisfied for approval. A member may switch to these therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.
 - III. Increasing call center capacity, including pharmacy help desk lines, to respond to an anticipated increase in call volume from affected members regarding Navitus' and/or Part D Plan Sponsor's transition process.
 - IV. Making arrangements to continue to provide necessary drugs to a member by extending the transition period, on a case-by-case basis, if the member's exception request or appeal has not been processed by the end of the minimum transition period.
3. Our transition processes will apply to all new prescriptions for a non-formulary drug. If Navitus is unable to make a distinction between a new prescription and an ongoing prescription for a non-formulary drug at the point-of-sale, we will provide the enrollee with a transition fill.
4. Timeframes for Transitional Fills:
- A. Temporary Fills
 - I. Within the first 90 days of coverage for a new member under a Part D plan, Navitus will provide a temporary fill when our new member requests a refill of a non-formulary drug, including Part D drugs that are on Part D formulary but require prior authorization, exceed quantity limits, or require step therapy under this medication utilization management policy.
 - II. This 90 day timeframe applies to retail, home infusion, long term care and mail order pharmacies.
 - III. Since certain members may join a plan at any time during the year, this requirement will apply beginning on a member's first effective date of coverage, and not only to the first 90 days of the contract year.
 - IV. If an enrollee leaves a plan and re-enrolls during the original 90 day transition period, the transition period begins again with the new effective date of enrollment. However, if there is no gap in coverage, there is no new transition period.
 - V. This 90 day timeframe assists those beneficiaries transitioning from other prescription drug coverage who obtained extended (i.e., 90-day) supplies of maintenance drugs prior to the last effective date of their previous coverage.
 - B. Outpatient Setting (Retail Pharmacies) – The temporary supply of non-formulary Part D drugs, including Part D drugs that require prior authorization, exceed quantity limits, or require step therapy under Navitus' or Plan Sponsor's utilization management policy, must be for at least a month's supply of medication.
 - I. If the enrollee presents with a prescription written for less than a month's supply, Navitus will allow multiple fills to provide at least a month's supply of medication.
 - II. Allow for multiple fills for unbreakable packages that will allow at least a a month's supply to be dispensed during a beneficiary's transition.

C. Long-Term Care (LTC) Setting – The temporary supply of non-formulary Part D drugs, including Part D drugs that require prior authorization, exceed quantity limits, or require step therapy under Navitus' or Plan Sponsor's utilization management policy, for a new member in a LTC facility for at least a month's supply consistent with the dispensing increments (unless the prescription is written for less), with refills provided if needed during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.

- I. Navitus will not use early refill edits to limit enrollees being admitted to or discharged from a LTC facility from appropriate and necessary access to their Part D benefit and such enrollees are allowed access to a refill upon admission or discharge.
- II. Refer to Section 6 - Emergency Supply for Current Members below regarding LTC Emergency Supply

D. Transition Extension:

- I. Navitus will make arrangements, as necessary, to continue to provide necessary drugs to a member via an extension of the transition period. If the decision is made to allow an extension by a Navitus clinician or the Plan Sponsor, an override will be entered in the pharmacy processing (Navicclaim Rx) system by Navitus Member Services.
- II. This extension is granted on a case-by-case basis taking into account whether the member's exception request or appeal has not been processed by the end of the minimum transition period.
- III. Navitus and the Plan Sponsor provides clear guidance to the affected members in the transition notice sent to members, explaining how to proceed after a temporary fill is provided, so that an appropriate and meaningful transition can be effectuated by the end of the transition period.
- IV. Navitus recognizes that until the transition is actually made, either through a switch to an appropriate formulary drug or a decision is made regarding an exception request, continuation of drug coverage is necessary (other than for drugs not covered under Part D).

5. Transition Across Contract Years

- A. After members receive their ANOC by September 30th of a given year, Navitus' transition policy requires that a Plan Sponsor select at least one of the following two options for effectuating an appropriate and meaningful transition for members whose drugs are affected by negative formulary changes from one contract year to the next:
 - I. Provide a transition process for current members at the start of the new contract year. In order to prevent coverage gaps, should this option be selected, Navitus will provide a temporary supply of the requested prescription drug and provide our affected members with the required transition notice; or
 - II. Effectuate a transition for current members prior to the start of the new contract year. If this option is selected, Navitus will aggressively work to:
 - i. Prospectively transition current members to a therapeutically equivalent formulary alternative; and
 - ii. Complete any requests for exceptions to the new formulary prior to the start of the contract year.
 - a. If Navitus or the Plan Sponsor approves an exception request, we will authorize payment prior to January 1st of the new contract year

- b. If, however, Navitus or the Plan Sponsor has not successfully transitioned affected members to a therapeutically equivalent formulary alternative or processed an exception request by January 1st, we will provide a transition supply (and the required transition notice) beginning January 1st and until such time as it has effectuated a meaningful transition.

- B. Current Enrollees: Where Navitus can identify objective information demonstrating that a meaningful transition has occurred or the enrollee lacks documented ongoing therapy, we do not have to provide access to a transition supply in the new contract year for that member. Objective information includes:
 - I. Processing an exception request
 - II. Evidence of a new prescription claim for a formulary alternative processed prior to the start of the contract year
 - III. Greater than 108 days of eligibility with no claims history in the last 180 days from the prescription date of service

However, if Navitus is unable to identify such objective evidence, we will provide a transition supply in the new contract year and provide the required transition notice.

- C. New Enrollees: Navitus and Plan Sponsor also extends the transition policy across contract years where a member enrolls into one of our plans with an effective enrollment date of either November 1st or December 1st and that member needs access to a transition supply.
 - I. In addition, Navitus or Plan Sponsor will send these members, with a November 1st or December 1st effective enrollment date, an ANOC as soon as practicable after the effective enrollment date.
 - II. The ANOC will still serve as advance notice of any formulary or benefit changes in the following contract year.

6. Emergency Supply for Current Members

- A. Navitus' transition policy covers emergency supplies of non-formulary Part D drugs for LTC facility residents.
- B. During the first 90 days after a member's enrollment, he/she will receive a transition supply. However, to the extent that a member in an LTC setting is outside his/her 90-day transition period, Navitus and/or the Plan Sponsor will provide an emergency supply of non-formulary Part D drugs, including Part D drugs that are on Navitus' or the Plan Sponsors Part D formulary that would otherwise require prior authorization, exceed quantity limits, or require step therapy under utilization management policy, while an exception or prior authorization is requested.
- C. These emergency supplies of non-formulary Part D drugs will be for at least 31 days of medication, regardless of dispensing increments, unless the prescription is written by a prescriber for less than 31 days.
- D. In cases where the smallest available marketed package size is not available for less than a 31-day supply, Navitus will still provide an emergency supply when required.

7. Level of Care Changes

- A. Navitus' transition process provides for other circumstances that exist in which unplanned transitions for current members could arise and in which prescribed drug regimens may not be on our formulary. These circumstances usually involve the level of care changes for a member that is changing from one treatment setting to another, such as:
 - I. Members who enter LTC facilities from hospitals with a discharge list of medications from the hospital formulary with very short term planning taken into account (i.e. under 8 hours)
 - II. Members who are discharged from a hospital to a home with very short-term planning taken into account
 - III. Members 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
 - IV. Members who give up hospice status to revert to standard Medicare Part A and B benefits
 - V. Members who end an LTC facility stay and return to the community
 - VI. Members who are discharged from psychiatric hospitals with drug regimens that are highly individualized
- B. The foregoing circumstances often result in members and/or providers utilizing Navitus' or the Plan Sponsor's exceptions and/or appeals processes. For these unplanned transitions, Navitus and/or the Plan Sponsor make coverage determinations and re-determinations as expeditiously as the member's health condition requires.
- C. Navitus' transition process ensures appropriate medication reconciliation for member upon discharge from LTC facilities or other facilities, so that an effective transition of care can be accomplished.
 - I. The current standard of care promotes caregivers receiving outpatient Part D prescriptions in advance of discharge from a Part A stay. Members, through no fault of their own, may not have access to the remainder of the previously dispensed prescription.
 - II. Navitus' process allows the member to access a refill upon admission to, or discharge from, a LTC facility.
- D. Navitus uses claims data to determine if the member has experienced a level of care change and allows a transition fill where applicable. When claims data cannot be used to determine a level of care change, a pharmacy may need to call Navitus Member Services to process a point-of-sale override in order to effectuate this type of transition fill.

8. Edits for Transitional Fills

- A. Navitus' transition process ensures that a new member is able to leave a network pharmacy with a temporary supply of non-formulary Part D drugs without unnecessary delays.
- B. Navitus applies certain drug utilization management edits during a member's transition period. Drug utilization management edits that are appropriate during a member's transition period include the following:
 - I. Edits to help determine Part A or B versus Part D coverage

- II. Edits to prevent coverage of non-Part D drugs (i.e., excluded drugs or formulary drugs being dispensed for an indication that is not medically accepted)
 - III. Utilization Review Edits to promote safe utilization of a Part D Drug (i.e., member-level opioid claim edit, quantity limits based on FDA maximum recommended daily dose, early refill edits)
- C. While Navitus may implement step therapy, prior authorization or quantity limits edits during transition, we only do so if the edits are resolved at the point of sale.
- I. Our adjudication system is set up so that all non-formulary Part D drugs and all drugs requiring utilization management edits will process automatically for a member in their transition period. Our adjudication processing system, for a claim for a beneficiary in their transition period, will bypass all edits except those described in Section 8b.
 - II. During transition, Navitus allows overrides to these edits if the prescriber will not authorize the change at point of sale.
 - III. If the edit is overridden only for transition purposes, the member will be notified so that he/she can begin the exception process, if necessary.
- D. Navitus and/or the Plan Sponsor may implement quantity limits that are based on approved product labeling during a member's transition period. Navitus will provide 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 to meet the transition supply requirement. Irrespective of transition, all edits are subject to exceptions and appeals.
- I. Navitus' and Plan Sponsors' transition process ensures that affected members are made aware of quantity limits and the fact that an exception is required to obtain a greater quantity.
 - II. Navitus or the Plan Sponsor expeditiously processes all exception requests so that members will not experience unintended interruptions in medically-necessary Part D drug therapies and/or will not inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.
 - III. Member-level opioid point-of-sale claim edits (and cumulative opioid MED edits) may be applied during transition.
- E. To meet CMS' intent for messaging to pharmacies for transition fill notices at point of sale, in accordance to Chapter 6 Sec. 30.4.10 and Chapter 14 Sec. 50.5, Navitus has implemented enhanced transition fill messaging functionality in the claims adjudication system. This provides messaging to the submitting pharmacy with notification of a transition fill for the beneficiary.
9. Cost-Sharing Considerations
- A. Navitus and Plan Sponsors will charge cost-sharing for a temporary supply of drugs provided under our transition process.
 - B. Cost-sharing for transition supplies for low-income subsidy (LIS) eligible members can never exceed the statutory maximum co-payment amounts.

- C. For non-LIS eligible enrollees:
 - I. Navitus or Plan Sponsor charges cost-sharing for a temporary supply of drugs provided under its transition process based on one of our approved drug cost-sharing tiers (if the sponsor has a tiered benefit design). This cost-sharing is consistent with cost-sharing that Navitus or Plan Sponsor would charge for non-formulary drugs approved under a coverage exception.
 - II. The same cost sharing for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met.

10. Transition Notices

- A. Navitus or the Plan Sponsor sends written notice consistent with CMS transition requirements to members (as noted in 10.b. below) within three business days after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on Part D formulary but require prior authorization, exceed quantity limits, or require step therapy under utilization management policy). If the enrollee completes the transition supply in several fills, Navitus will send the notice with the first fill only. All transition notices include:
 - I. An explanation of the temporary nature of the transition supply the member or new enrollee has received
 - II. Instructions for working with Navitus or Plan Sponsor and the prescribing clinician to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the respective Part D formulary
 - III. An explanation of the member's right to request a formulary exception including processing timeframes and the member's right to request an appeal if the exception decision is unfavorable
 - IV. A description of the procedure for requesting a formulary exception
 - V. 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 3 business days after adjudication of the first temporary fill.
- B. The appropriate transition letter, based on the reason for the initial denial of the medication, is sent via U.S. First Class mail to each member, who receives a transition fill.
 - I. Navitus will use the CMS model Transition Notice.
 - II. Navitus makes prior authorization and exception request forms available (upon request via mail, fax, or email, and are available on Navitus' or the Plan Sponsor's web site) to both members and prescribing physicians.
- C. Navitus provides the prescriber of record with a copy of the transition notice that was sent to the member labeled "PRESCRIBER COPY" via U.S. first class mail or fax.
- D. Navitus and Plan Sponsors make general information about the transition processes available to members on the plan sponsor web site, along with a link to CMS' Medicare Prescription Drug Plan Finder relating to plan transition process information. Plan sponsors also include transition process information in pre- and post-enrollment marketing materials as directed by CMS.

11. Navitus Pharmacy & Therapeutics Committee Role in Transition

- A. Navitus has procedures for medical review of non-formulary drug requests and, when appropriate, a process for switching new Navitus Part D members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.
- B. The Navitus P&T Committee reviews and provides recommendations regarding the procedures for medical review of non-formulary drug requests.
- C. The Navitus P&T Committee's involvement ensures that transition decisions appropriately address situations involving members stabilized on drugs that are not on Navitus' Part D formulary (or that are on the formulary but require prior authorization, exceed quantity limits, or require step therapy under utilization management policy) and which are known to have risks associated with any changes in the prescribed regimen.
- D. The Navitus P&T Committee's supporting policies and procedures for medical review of non-formulary drug requests and alternative medications include:
 - I. P&T Review Process – Formulary Development
 - II. Formulary Administration Process
 - III. Medicare Part D Coverage Determinations
 - IV. Automated Review Program
 - V. Clinical Decision Support Tools

12. All Navitus Health Solutions logs and documentation will be stored per NHS data retention policies for minimum period of ten (10) years subject to review by Plan Sponsor(s), CMS and other authorized entities. All applicable Plan Sponsor(s) logs and documentation will be stored at the Plans Sponsor(s) campus for a minimum period of ten (10) years.