



<b>Title:</b>	Formulary Transition Process				
<b>Department/Line of Business:</b>	Pharmacy/Medicare Operations				
<b>Approver(s):</b>					
<b>Location/Region/Division:</b>	SWHP				
<b>Document Number:</b>	SWHP.FC DPS.200.P				
<b>Effective Date:</b>	01/01/2021	<b>Last Review/ Revision Date:</b>	05/31/2020	<b>Origination Date:</b>	01/01/2019

## LINE OF BUSINESS

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

FirstCare Medicare Advantage

## DEFINITIONS

*When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document.*

**Center for Medicare and Medicaid Services** Government agency charged with overseeing the Medicare Part D program

**Pharmacy and Therapeutics (P&T) Committee** An advisory committee, meeting quarterly, that is responsible for reviewing clinical information regarding medications and making formulary recommendations. 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 employees of Navitus nor FirstCare.

## POLICY

In accordance with CMS guidance, FirstCare, a part of Baylor Scott and White Health, has a transition process to allow enrollees whose current drug therapies may not be included on the FirstCare Medicare Part D formulary(s) to continue drug therapy while transitioning onto the FirstCare Medicare Part D prescription plans. FirstCare utilizes Navitus Health Solutions' standard Transition process. Navitus has system capabilities in place to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as allow the plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.

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 Implementation Statement

FirstCare, a part of Baylor Scott and White Health, 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, FirstCare 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 FirstCare 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. The section VIII of this policy describes the edits, adjudication processes, and pharmacy notification processes.

Our PBM's 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 adjudication system will apply the edits noted above and in Section VIII.b., 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, we have an 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.

**I. Members and situations affected** by this transitional fills policy in which FirstCare will apply a transition process consistent with 42 CFR §423.120(b)(3) as detailed in the policy below:

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

## II. General Guidelines

1. The transition process is applicable to:
  - a. Part D drugs that are not on Part D formulary
  - b. Part D drugs that are on Part D formulary but require prior authorization, exceed quantity limits or require step therapy under the utilization management rules.
2. FirstCare 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:
  - a. Analyzing claims data to determine which members require information about their transition supply.
  - b. 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.
    - 1) 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.

- 2) 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.
- c. Increasing call center capacity, including pharmacy help desk lines, to respond to an anticipated increase in call volume from affected members regarding FirstCare's transition process.
- d. 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.

**III. FirstCare transition processes** will apply to all new prescriptions for a non-formulary drug. If we are 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.

#### **IV. Timeframes for Transitional Fills:**

##### **1. Temporary Fills**

- a. Within the first 90 days of coverage for a new member under a Part D plan, FirstCare 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.
- b. This 90 day timeframe applies to retail, home infusion, long term care and mail order pharmacies.
- c. 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.
- d. 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.
  - 1) 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.

##### **2. 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 FirstCare's utilization management policy, must be for at least a month's supply of medication.

- a. If the enrollee presents with a prescription written for less than a month's supply, we will allow multiple fills to provide at least a month's supply of medication.
- b. Allow for multiple fills for unbreakable packages that will allow at least a month's supply to be dispensed during a beneficiary's transition.

##### **3. 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 the 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.

- a. FirstCare 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.
- b. Refer to Section 6 - *Emergency Supply for Current Members* below regarding LTC Emergency Supply

##### **4. Transition Extension:**

- a. FirstCare 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 our designated clinician, an override will be entered in our PBM's pharmacy processing system by Member Services.
- b. 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.
- c. FirstCare 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.
- d. FirstCare 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).

## V. Transition Across Contract Years

- a. After members receive their Annual Notice of Change (ANOC) by September 30<sup>th</sup> of a given year, FirstCare effectuates an appropriate and meaningful transition for members whose drugs are affected by negative formulary changes from one contract year to the next by providing a transition process for current members at the start of the new contract year. FirstCare will provide a temporary supply of the requested prescription drug and provide our affected members with the required transition notice.
- b. Current Enrollees: Where we 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:
  - 1) Processing an exception request
  - 2) Evidence of a new prescription claim for a formulary alternative processed prior to the start of the contract year
  - 3) Greater than 108 days of eligibility with no claims history in the last 180 days from the prescription date of service

However, if we are 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: FirstCare 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 1<sup>st</sup> or December 1<sup>st</sup> and that member needs access to a transition supply.
  - 1) In addition, FirstCare will send these members, with a November 1<sup>st</sup> or December 1<sup>st</sup> effective enrollment date, an ANOC as soon as practicable after the effective enrollment date.
  - 2) The ANOC will still serve as advance notice of any formulary or benefit changes in the following contract year.

## VI. Emergency Supply for Current Members

1. FirstCare's transition policy covers emergency supplies of non-formulary Part D drugs for LTC facility residents.
2. 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, we will provide an emergency supply of non-formulary Part D drugs, including Part D drugs that are on FirstCare's 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.
3. 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.
4. In cases where the smallest available marketed package size is not available for less than a 31-day supply, we will still provide an emergency supply when required.

## VII. Level of Care Changes

1. FirstCare's 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:
  - a. 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)
  - b. Members who are discharged from a hospital to a home with very short-term planning taken into account
  - c. 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
  - d. Members who give up hospice status to revert to standard Medicare Part A and B benefits
  - e. Members who end an LTC facility stay and return to the community
  - f. Members who are discharged from psychiatric hospitals with drug regimens that are highly individualized
2. The foregoing circumstances often result in members and/or providers utilizing FirstCare's exceptions and/or appeals processes. For these unplanned transitions, we will make coverage determinations and re-determinations as expeditiously as the member's health condition requires.
3. FirstCare's 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.
  1. 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.
  2. FirstCare's process allows the member to access a refill upon admission to, or discharge from, a LTC facility.
4. FirstCare 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 Member Services to process a point-of-sale override in order to effectuate this type of transition fill.

## VIII. Edits for Transitional Fills

1. FirstCare's 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.
2. FirstCare 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:
  - a. Edits to help determine Part A or B versus Part D coverage
  - b. 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)
  - c. 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)
3. While FirstCare 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.
  - a. 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.
  - b. During transition, FirstCare allows overrides to these edits if the prescriber will not authorize the change at point of sale.

- c. 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.
4. FirstCare may implement quantity limits that are based on approved product labeling during a member's transition period. FirstCare 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.
  - a. FirstCare's 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.
  - b. FirstCare 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.
  - c. Member-level opioid point-of-sale claim edits (and cumulative opioid MED edits) may be applied during transition.
5. 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, FirstCare's PBM 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.

## IX. Cost-Sharing Considerations

1. FirstCare will charge cost-sharing for a temporary supply of drugs provided under our transition process.
2. Cost-sharing for transition supplies for low-income subsidy (LIS) eligible members can never exceed the statutory maximum co-payment amounts.
3. For non-LIS eligible enrollees:
  - a. FirstCare 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 FirstCare would charge for non-formulary drugs approved under a coverage exception.
  - b. 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.

## X. Transition Notices

1. FirstCare 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, FirstCare will send the notice with the first fill only. All transition notices include:
  - a. An explanation of the temporary nature of the transition supply the member or new enrollee has received
  - b. Instructions for working with FirstCare and the prescribing clinician to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the respective Part D formulary
  - c. 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
  - d. A description of the procedure for requesting a formulary exception
  - e. 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.

2. 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.
  - a. FirstCare will use the CMS model Transition Notice.
  - b. FirstCare makes prior authorization and exception request forms available (upon request via mail, fax, or email, and are available on FirstCare' or our PBM's web site) to both members and prescribing physicians.
3. FirstCare 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.
4. The transition processes available to members on our web site, along with a link to CMS' Medicare Prescription Drug Plan Finder relating to plan transition process information. FirstCare also include transition process information in pre- and post-enrollment marketing materials as directed by CMS.

## **XI. FirstCare's PBM Pharmacy & Therapeutics Committee Role in Transition:** FirstCare delegates the formulary and criteria management to our PBM.

1. The Committee has procedures for medical review of non- formulary drug requests and, when appropriate, a process for switching new Part D members to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.
2. The PBM's P&T Committee reviews and provides recommendations regarding the procedures for medical review of non-formulary drug requests.
3. The PBM's P&T Committee's involvement ensures that transition decisions appropriately address situations involving members stabilized on drugs that are not on FirstCare's 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.
4. The PBM's P&T Committee's supporting policies and procedures for medical review of non-formulary drug requests and alternative medications include:
  - a. P&T Review Process – Formulary Development
  - b. Formulary Administration Process
  - c. Medicare Part D Coverage Determinations
  - d. Automated Review Program
  - e. Clinical Decision Support Tools

**XII. All logs and documentation will be stored** by the PBM's data retention policies for minimum period of ten (10) years and is subject to review by FirstCare, CMS and other authorized entities. All applicable FirstCare specific logs and documentation will be stored at the FirstCare (Part of Baylor Scott and White) campus for a minimum period of ten (10) years.

## **ATTACHMENTS**

None.

## **RELATED DOCUMENTS**

None.

## **REFERENCES**

- Navitus Health Solutions CY2021 Formulary Transition Process

The information contained in this policy is confidential and proprietary and may not be shared without the express permission of the Scott and White Health Plan. Further, the information contained in this document should not be considered standards of professional practice or rules of conduct or for the benefit of any third party. This document is intended to provide guidance and, generally, allows for professional discretion and/or deviation when the individual health care provider or, if applicable, the "Approver" deems appropriate under the circumstances.



<b>Attachment Name:</b>			
<b>Attachment Number:</b>		<b>Last Review/Revision Date:</b>	05/30/2019