Classification:	Clinical Department	Policy Number:	3404.00
Subject:	Medicare Part D – General Transition Process	Effective Date:	01/01/2019
		Date Revised:	05/24/2019
		Date Reviewed:	05/24/2019

POLICY STATEMENT:

CastiaRx maintains a transition process consistent with 42 CFR §423.120(b)(3) to assist beneficiaries who are transitioning from drug regimens or therapies that may not be included in the Part D Plan Sponsor's formulary to medications that are on the formulary of the Part D Plan Sponsor, so that an eligible beneficiary will leave the pharmacy with a filled transitional supply of a Part D eligible prescription drug. CastiaRx understands that in some cases a member may be stabilized on their medication regimen and therefore, in order to ensure a smooth transition process for beneficiaries, CastiaRx has adopted a transition process that will effectuate a meaningful transition for:

- new enrollees into prescription drug plans following the annual coordinated election period,
- newly eligible Medicare beneficiaries from other coverage,
- enrollees switching from one plan to another after the start of a contract year,
- current enrollees affected by negative formulary changes across contract years,
- and enrollees residing in LTC facilities.

The transition program system logic allows for edits to be automatically over-ridden at the point of sale without intervention from the pharmacy or CastiaRx.

PROCEDURE:

CastiaRx will temporarily cover non-formulary drugs, which include;

1) Part D drugs not on a plan's formulary,

2) Part D drugs that are on a plan's formulary but require prior authorization or step therapy, or that have an approved quantity limit lower than the beneficiary's current dose, under a plan's utilization management rules.

CastiaRx maintains systems capabilities to provide a temporary supply of medication to accommodate the immediate need of the beneficiary and to allow CastiaRx and/or the beneficiary sufficient time to work with the prescriber to switch to an equivalent alternative or file for a coverage determination to maintain coverage of an existing medication based on medical necessity. CastiaRx's systems capabilities include overriding non-formulary, prior authorization, and step therapy rules. The transitional claim override will take place immediately upon the patient's presentation to the pharmacy with no need for pharmacy input of over-ride codes at the point of sale to activate the transition process. Messaging will occur at the point-of-sale notifying pharmacy providers that a transition claim processed under the transition program.

Messaging will be similar, but not limited to the notations below:

CLAIM FILLED BY TRANSITION-PA RQRD on NEXT FILL

CLAIM FILLED BY TRANSITION-ST RQRD on NEXT FILL

CLAIM FILLED BY TRANSITION-NON FORM DRUG

CLAIM FILLED BY TRANSITION-QTY LIMIT

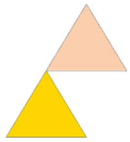
CastiaRx will continue to monitor NCPDP standards organizations for future developments of new messaging or until alternative transactional coding is implemented and adopted by NCPDP standards. Until alternative transactional coding is implemented and adopted by NCPDP standards, CastiaRx has a point of sale process that provides point of sale messaging to the pharmacy providers in the NCPDP Response Claim Message to indicate that "TRANSITION MAY APPLY TO THE CLAIM" to alert the pharmacy of transitions, as well as utilizes the prior authorization segment of NCPDP vD.0 field numbers: 461-EU and 462-EV to activate the transition. All transition processes will be applied to a brand-new prescription for a non-formulary drug if it cannot be distinguished whether it is a brand-new prescription for a non-formulary drug or an ongoing prescription for a non-formulary drug at the point of sale. Products falling into this category of coverage shall be provided to the beneficiary at the co-payment specified in the Plan's Annual BID to CMS. Except for the smallest available marketed package size products, any provider who wishes to exceed the approved month's supply will need to request a prior authorization for coverage of the non-formulary product for reasons of medical necessity.

The Plan Sponsor and CastiaRx will notify beneficiaries of changes between contract years and make efforts to transition a beneficiary to a formulary alternative or therapeutically equivalent drug. Tools such as the Annual Notice of Change (ANOC) and member letters or phone calls are used; however for current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, CastiaRx will effectuate a meaningful transition process at the start of the new contract year. This not only includes drugs that were removed from the formulary from year to year but also drugs that had a utilization management edit added such as a step therapy or prior authorization requirement or an approved quantity limit lower than the beneficiary's current dose.

Enrollees have the right to request an exception to a Plan Sponsor's formulary at any point during the coverage year. CastiaRx will maintain a process for an enrollee to request an exception for those beneficiaries that are unable to switch to an appropriate therapeutic alternative after having filled a medication under the transition policy. Exception requests can be submitted to CastiaRx by telephone, fax, mail, or online. The first step in requesting an exception to a Plan Sponsor's coverage rule is for an enrollee to ask their prescriber to submit a statement supporting their request. The prescriber's statement should indicate that the requested drug is medically necessary for treating their condition because none of the drugs on the Plan Sponsor's formulary would be as effective as the requested drug or would have adverse effects. A submitted request will be reviewed under the appropriate timeframes established by CMS in Chapter 18 §30.2 of the Prescription Drug Benefit Manual. If CastiaRx finds there is a lack of evidence to support approval of an exception request, CastiaRx will notify the beneficiary and prescriber via phone, mail, and/or fax of the rationale behind the denial and provide therapeutic formulary alternatives for the beneficiary's condition, if appropriate. The information mailed to the beneficiary and provider will also contain information regarding how to submit an appeal for the requested medication.

CastiaRx will support Plan Sponsors in making the transition policy available to enrollees via Web links from the Medicare Prescription Drug Plan Finder to sponsor websites as well as including information in pre and post enrollment marketing materials as directed by CMS.

For beneficiaries when CastiaRx is unable to distinguish between a new non-formulary drug prescription and an ongoing non-formulary drug prescription at the point of sale, or for beneficiaries that are auto-enrolled into the



part D program, CastiaRx shall enact the following procedure:

RETAIL SETTING

Beneficiaries who are within their first 90 days of coverage under a new plan are determined as eligible for transition using the beneficiary coverage start date or effective date with the plan. This is the date the beneficiary is enrolled in the specific Plan Benefit Package (PBP) to account for re-enrollments and PBP changes. For beneficiaries who have had continuous enrollment in a PBP, the assigned start date for the program is determined by providing a look back comparison to the Group or Plan Start Date which is set on an annual basis per the CMS Annual PBP specification. In these cases, a later of logic is employed to use the beneficiary's PBP effective date or the Group PBP Plan Start date, whichever is later, to ensure that all appropriate members are noted as eligible for a transitional benefit.

1. All claims for non-formulary, prior authorization required, step therapy, or quantity limited medications (up to the FDA maximum dosage) will process at the copayment specified in the plan's annual BID to CMS.

2. The transition process will be applied at the point of sale for at least an approved month's supply in accordance with the plan's bid (unless Rx is written for less than an approved month's supply in which case multiple refills to provide up to the approved month's supply of meds is allowed when required) anytime during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage.
3. Continuing members impacted by formulary and/or utilization management edits are included in this policy, as well as beneficiaries who switch enrollment from one Plan Sponsor to another as the first ninety (90) days of enrollment is determined from the beneficiary's effective date with the Part D Plan Sponsor. The transition process will be extended across contract years if a beneficiary enrolls in a Plan with an effective enrollment date of either November 1 or December 1 and requires access to a transition supply.

4. The cost-sharing for a temporary supply of medication will never exceed the statutory maximum co-payments established for low-income subsidy qualified (LIS) beneficiaries. For non-LIS eligible enrollees, cost-sharing for drugs provided under the transition process will be consistent with cost-sharing that would be charged for:

- non-formulary drugs approved under a formulary exception in accordance with 42 CFR §423.578(b) and
- formulary drugs subject to utilization management edits that would apply if the utilization management criteria are met.

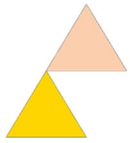
5. CastiaRx has edits in place that will ensure that transitional supplies are not automatically filled for Part A or B versus Part D eligible drugs, statutorily excluded drugs, FDA NDC Non-matched drugs, DESI drugs, and non-Part D drugs. CastiaRx also utilizes edits during transition at the point of sale that are designed to promote safe utilization of Part D drugs (i.e. quantity limits on FDA maximum dosages). Step therapy and prior authorization edits are resolved at the point of sale automatically via the transition logic.

System logic during the transition period evaluates the insured effective date to determine if the beneficiary is eligible for transition. CastiaRx's transition policy during a new coverage year treats new and continuing beneficiaries differently. After the system determines an enrollee is transition eligible, it then determines if the medication being submitted is limited from transition eligibility due to 1 of the 3 criteria outlined by CMS in Chapter 6 §30.4.8 of Prescription Drug Benefit Manual. The 3 criteria include;

A. edits to help determine Part A or Part B vs. Part D coverage;

B. edits to prevent coverage of a non-part D drug; and

C. edits to promote safe utilization of a part D drug (e.g., FDA maximum quantity limits).



These are the only edits that CastiaRx employs during an enrollee's eligible transition period that would prevent a claim from processing automatically at the point of sale. All other utilization management edits (e.g., step therapy, prior authorization) are relaxed at the point of sale during a transition eligible period and are allowed to process at the point of sale with no overrides being required.

6. CastiaRx will send the CMS approved model written transition notice via U.S. first class mail to the enrollee within three business days of adjudication of a temporary transition fill with a copy of the written transition notice to the prescribing physician of the transition claim. The notice is sent on all transitional supply claims filled at both the retail and LTC care setting [this includes long-term care residents dispensed multiple supplies of a Part D drug in increments of 14-days-or-less consistent with the requirements under 42CF$423.154(a)(1)(i)]. The notice will include:

A. an explanation of the temporary nature of the transition supply an enrollee has received,
B. instructions for working with CastiaRx and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary,
C. an explanation of the enrollee's right to request a formulary exception, the timeframes for processing the exception, and the enrollee's right to request an appeal if the decision is unfavorable, and
D. a description of the procedures for requesting a formulary exception.

CastiaRx utilizes the model Part D Transition Notice to detail;

A. member services contact information,
B. hours of operation,
C. instructions on how to apply for an exception and
D. how to change a current prescription to a formulary alternative.

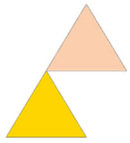
The Model transition notice will be supplied to Plan Sponsors to file under the file-and-use process for marketing review. CastiaRx will make available prior authorization or exceptions request forms upon request to both enrollees and prescribers via a variety of mechanisms, including mail, fax, email, included in pre and post marketing materials as directed by CMS, plan web sites, and links from the Medicare Prescription Drug Finder to the Plan Sponsor's web site. CastiaRx makes general information about its transition process available to members in plan enrollment materials, its official Web Site, as well as via a link to its official Web Site from the Medicare Prescription Drug Plan Finder.

7. CastiaRx provides a copy of the written transition notice labeled as the "PRESCRIBER COPY" directly to the prescriber of record via US Mail. For mail that is returned as undeliverable to prescribers, CastiaRx will attempt via other reasonable means to provide a copy of the notice to the prescriber via mail, fax, or electronic means, when possible, and feasible.

8. Beneficiaries that submit a request for prior authorization for medical review that applies to a non-formulary medication will have to meet specific requirements prior to allowing coverage. For non-formulary medications that are denied through the prior authorization process, therapeutically appropriate formulary alternatives will be provided to the enrollee and the prescribing physician.

9. CastiaRx 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, where the enrollees' exception request or appeals have not been processed by the end of the minimum transition period, and until the transition has been made whether through a switch of formulary drug or a decision on an exception request.

10. For medications requiring a quantity limitation due to manufacturer or FDA approved maximum dosages safety concerns, beneficiaries will be allowed to obtain a supply of medication that is within the FDA approved dosage schedule. CastiaRx will take efforts to ensure the beneficiary is aware of the limit and the process for obtaining an exception. CastiaRx will allow for refills of up to at least an approved month's supply in accordance with plan bid in an



outpatient setting and the LTC setting. For example, if a beneficiary presents at a retail pharmacy with a prescription for 1 tablet per day for 30 days and the plan has a quantity limit edit in place that limits the days' supply to 15 per prescription for safety purposes, the beneficiary would receive a 15-day supply (consistent with the safety edit). At the conclusion of the 15-day supply, the beneficiary is entitled to the remaining supply to fulfill an approved month's supply in accordance with plan bids while he/she continues to pursue an exception, or a switch to a therapeutic alternative on the plan's formulary.

11. CastiaRx allows for the transition process to be applied to a prescription fill for greater than an approved month's supply for smallest available marketed package size (SAMPS) products (or to subsequent claims for prescription fills for less than an approved month's supply if a smallest available marketed package size product is dispensed and the enrollee requires additional processing of claims to meet full transition of an approved month's supply). CastiaRx will routinely evaluate SAMPS products to determine whether an exception to the transitional approved months' supply applies.

LONG TERM CARE SETTING

For beneficiaries that reside in a Long Term Care setting or for claims that are submitted by contracted Long Term Care pharmacies with a Patient Location Code of 03 for Nursing Home or 04 for Long Term Care Facility, the transitional benefit will apply as follows:

1. Beneficiaries that reside, are being admitted to, or are being discharged from a skilled nursing facility or a long-term care facility are eligible to receive an approved month's supply of non-formulary Part D drugs under transition (unless the enrollee presents with a prescription written for less than the approved month's supply). The prescription drug should be dispensed incrementally as applicable under 42 CFR§423.154 and with multiple fills if needed under the transition policy during the first 90 days of a beneficiary's enrollment in a plan, beginning on the enrollee's effective date of coverage. After the 90 day transition period has expired, a 31 day emergency supply of non-formulary Part D drugs (unless the enrollee presents with a prescription written for less than 31 days) will be provided, if necessary, including Part D drugs that are on a sponsor's formulary that would otherwise require prior authorization or step therapy under a sponsor's utilization management rules, while an exception is being processed.

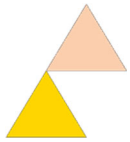
2. For enrollees who are being discharged from or admitted to a LTC facility, early refill edits can be over-ridden at the point of sale, so that beneficiaries are able to access a refill upon admission or discharge. In a LTC setting, CastiaRx does not use early refill edits to limit appropriate and necessary access to a Part D drug for an enrollee being admitted to or discharged from a LTC facility.

LEVEL OF CARE CHANGES

Exceptions are available for beneficiaries who have experienced a change in the level of care they are receiving which requires them to transition from one facility or treatment center to another. CastiaRx will make efforts to expedite transitions for enrollees who change treatment settings due to changes in level of care. 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 enrollees will be allowed to access a refill upon admission or discharge. Examples of situations in which beneficiaries would be eligible for the one-time temporary fill exception when they are outside of the ninety (90) day effective date into the Part D program are as follows:

a. A beneficiary is discharged from the hospital and is provided a discharge list of medications based upon the formulary of the hospital.

b. Beneficiaries who end their skilled nursing facility Medicare Part A stay (where payments include all pharmacy charges) and who need to revert back to their Part D plan formulary



c. Beneficiaries who give up Hospice Status to revert back to standard Medicare Part A and B benefits

d. Beneficiaries who are discharged from Chronic Psychiatric Hospitals with medication regimens that are highly individualized.

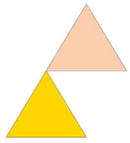
CastiaRx system logic will automatically review for automated changes to the CastiaRx Patient Location Code field to assist in the Identification of Level of Care Changes within the claims processing system parameters.

For claims submitted using NCPDP v5.1 Pharmacy Claims processing submissions, CastiaRx will utilize the following criteria to identify an automated level of care change:

FROM	TO
0= Not specified 1 = Home 10 = Outpatient 11 = Hospice 2 = Inter-Care 5 = Rest Home 6 = Boarding Home 7 = Skilled Care Facility 8 = Sub Acute Care Facility	3 = Nursing Home 4 = LTC

For claims submitted using NCPDP D.0 Pharmacy Claims processing submissions CastiaRx will utilize the following criteria to identify an automated level of care change:

FROM			TO
0 = Not specified 11 = Office Location 12 = Home 13 = Assisted Living Facility 14 = Group Home 15 = Mobile Unit 20 = Urgent Care Facility 21 = Inpatient Hospital 22 = Outpatient Hospital 23 = Emergency Room 24 = Ambulatory Surgical Center 25 = Birthing Center	26 = Military Treatment Facility 33 = Custodial Care Facility 34 = Hospice 49 = Independent Clinic 5 = IHS Freestanding Facility 50 = FQHC 51 = Inpatient Psychiatric Facility 52 = Psychiatric Facility 53 = Community Mental Health Center 54 = Intermediate Care Facility 55 = Residential Substance Abuse Treatment Center 56 = Psychiatric Residential Treatment Center	57 = Non-Residential Substance Abuse Treatment 6 = IHS Provider-Based Facility 60 = Mass immunization Center 61 = Comprehensive Inpatient Rehabilitation Facility 62 = Comprehensive outpatient Rehabilitation Facility 65 = ESRD Facility 7 = Tribal 638 - Free Standing 71 = Public Health Clinic 72 = Rural Health Clinic 8 = Tribal 638 Provider Based 99 = Other Place of Service	32 = Nursing Facility 31 = Skilled Nursing Facility



Additional point of sale messaging will also be employed to identify possible level of care changes, with the following message depending upon NCPDP claims messaging order priorities: IF LEVEL OF CARE CHANGE CALL HELP DESK.

GENERAL INFORMATION

Part D drugs eligible for coverage under the transition process will be defined as per 42 CFR 423.100.

Any beneficiary with a unique or extenuating circumstance not addressed in the above noted policy and procedure or beneficiaries in which an extension of the transition period is needed will be reviewed on a case by case basis. This is consistent with Chapter 6 §30.4.4.3 whereby CastiaRx will allow for an extension of the transition period by allowing a temporary fill. This would apply in those instances in which a beneficiary has initiated an exception request or appeal that has not yet been determined prior to the beneficiary running out of the necessary drug, or in those cases where an extension of the transition period is needed in order to maintain coverage of an existing drug based on medical necessity reasons. In addition, the transition notice that the beneficiary and prescriber receive details how to contact the CastiaRx pharmacy help desk 24 hours a day, 7 days a week for any questions or concerns about the identified medication. The CastiaRx pharmacy help desk is trained on how to identify those cases in which an immediate fill of medication is required and how to facilitate a temporary fill of medication in those cases where a beneficiary is waiting on a decision regarding an exception request, where continuation is needed for medical necessity reasons, or making a switch to an appropriate formulary drug.

CastiaRx will work with Plan Sponsors to perform routine auditing and quality assurance checks on the transition process as reasonable and best effort attempts to verify that the transition policy is correctly implemented in the claims system and that beneficiaries are receiving their required transition supplies.

CastiaRx provides Plan Sponsors with rejection and transition claims reporting for Plan Sponsor review. Reviews are conducted for situations in which a claim may have been rejected that should have processed for a beneficiary under transition. Claims paid under the transitional benefit are also reviewed to ensure these claims are for appropriate transitional situations.