Classification:	Clinical Department	**Policy Number**:	3404.00
Subject:	Medicare Part D – General Transition Process	**Effective Date**:	01/01/2019
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POLICY STATEMENT:

CastiaRx shall provide an automated process to assist beneficiaries who are transitioning from drug regimens or therapies that are not covered on 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 Part D eligible transitional filled 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 the following transition process 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 beneficiaries who enrolled late in a plan across plan years, current enrollees affected by negative formulary changes across contract years, and enrollees residing in LTC facilities. The transition program allows for edits to be over-ridden at the point of sale.

PROCEDURE:

CastiaRx will temporarily cover non-formulary drugs, which include 1) Part D drugs not on a plan's formulary, 2) drugs previously approved for coverage under an exception once the exception expires, and 3) 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. The temporary transition fill will accommodate the immediate need of the beneficiary and to allow time for the beneficiary to discuss therapeutic options and alternatives with their healthcare provider or file for a coverage determination. CastiaRx's system capabilities to maintain coverage of an existing drug based on medical necessity reasons include the over-ride of non-formulary status or prior authorization or step therapy rules. The transitional claim override will take place immediately upon the patient's presentation to the pharmacy and that there is 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 claim processed under a transitional fill and that the claim processed under the transitional benefit. 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 "TRANSTITION MAY APPLY TO THE CLAIM" to alert 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 30-day time frame 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 make efforts to identify beneficiaries prior to their effective date that may be already stabilized on their medication therapy prior to their enrollment in the Medicare Part D program. CastiaRx and the Plan Sponsor will then provide to the beneficiary information on alternative formulary preferred or generic products. The Plan Sponsor and CastiaRx will also utilize other mechanisms to 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 Plan Sponsors will effectuate a meaningful transition process at the start of the new contract year therefore eliminating the need for identification of drug subject to a cross-contract year formulary change. 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. A Plan Sponsor 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 the Plan Sponsor 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 the Plan Sponsor finds there is a lack of evidence to support approval of an exception request the Plan Sponsor will outreach to the beneficiary and prescriber via phone and mail to discuss the rationale behind the denial and to discuss therapeutic formulary alternatives that the beneficiary may switch to. The information mailed to the beneficiary and provider will also contain the information on therapeutic formulary alternatives to switch to and 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 in which efforts to identify non-formulary medications are unsuccessful prior to plan start, or for beneficiaries that are auto-enrolled into the part D program, CastiaRx shall enact the following procedure:

RETAIL SETTING

For beneficiaries who are within their first 90 days of coverage under a new plan as determined by 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 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 for the exceptions tier.

2. The transition process will be applied at the point of sale for at least an approved month's supply in accordance with plan 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. Beneficiaries who switch enrollment from one Plan Sponsor to another are also included in this policy as the first ninety (90) days of enrollment is determined from the beneficiary's effective date with the Part D Plan Sponsor and continuing members impacted by formulary and or utilization management edits. 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, drugs provided under the transition process will be consistent with cost-sharing that would be charged for non-formulary drugs approved under a coverage exception on the plan's cost-sharing tiers and the same cost sharing for formulary drugs subject to utilization management edits provided during the transition 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 B drugs, members covered under Part A, statutorily excluded drugs, FDA NDC Non-matched drugs, DESI drugs, and Non-Part D drugs due to not signing of the Medicare Model Manufacturer Agreement or for over-rides on edits 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.

System logic during the transition period evaluates the insured effective date to determine if the beneficiary is eligible for transition. The Plan Sponsor's transition policy during a new coverage year treats both new and continuing beneficiaries the same and allows them to be eligible for transition during the first 90 days of the coverage year. 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, edits to help determine Part A or Part B vs. Part D coverage; edits to prevent coverage of a non-part D drugs; and edits to promote safe utilization of a part D drug (e.g., FDA maximum quantity limits). These are the only edits that the Plan Sponsor 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 written notice is sent for every claim that qualifies as a transitional fill via U.S. first class mail within three business days after adjudication of a temporary

fill. The notice will include an explanation of the temporary nature of the transition supply an enrollee has received, 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, an explanation of the enrollee's right to request a formulary exception, and a description of the procedures for requesting a formulary exception. CastiaRx utilizes the model Part D Transition Notice to detail member services contact information, hours of operation, instructions on how to apply for an exception and 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 having coverage allowed. For non-formulary medication that are denied through the prior authorization process, therapeutically appropriate formulary alternatives will be provide 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. CastiaRx and Plan Sponsors will review the Monthly Transition Reports to determine which beneficiaries have requested a Coverage Determination or have filled the claim with a formulary alternative or therapeutically alternative medication.

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, while this may be a lesser amount than requested, the beneficiary are able to refill the prescription and it will be allowed sooner than the limit provides. CastiaRx will also 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 a 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 with the Part D plan, or a switch to a therapeutic alternative that is on the plan's formulary.

11. CastiaRx allows for the transition process to be applied to a greater than an approved month's supply fill for smallest available marketed package size products (or to subsequent claims for a less than an approved month's supply fill 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).

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 discharged from a skilled nursing facility or a long-term care facility are eligible to receive an approved month's supply in accordance with plan bid fill of a non-formulary drug or drug subject to prior authorization or step therapy (unless the enrollee presents with a prescription written for less than the approved month's supply) 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 an 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 and LTC facility.

3. For beneficiaries who are in a Long Term Care setting, CastiaRx will automatically process multiple transitional fills up to the maximum of an approved month's supply in accordance with plan bid allowance.

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 three month 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 payment s 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 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 follows:

i. As defined in 42 CFR 423.100, covered Part D drugs are the following if used for medically accepted indications as defined in System (Section 1927(k)(6) of the Act).

1. Section 1927(k)(6) defines “medically accepted indication” to mean used for a covered outpatient drug which is approved by the federal Food and Drug Administration (FDA) as set forth in the Federal Food. Drug and Cosmetic Act or drugs consistent with the American Hospital Formulary Services Drug Information, United States Pharmacopeia-Drug Information and the DRUGDEX Information System.

2. A drug that may be dispensed only upon a prescription and that is described in Section 1927(k)(2(A)(i) through (iii).

ii. Section 1927(k)(2)(A)(i)-(iii) defines “covered outpatient drug” to mean a prescription drug which may be dispensed only upon prescription and

1. Which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

2. Which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

3. Which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling

iii. A biological product described in Section 1927(k)(2)(B)(i) through (iii). Section 1927(k)(2)(B)(i)-(iii) defines “biological product”, other than a vaccine, to mean a product which:

1. May only be dispensed upon prescription,

2. Is licensed under section 351 of the Public Health Service Act, and

3. Is produced at an establishment licensed under such section to produce such product.

iv. Insulin described in Section 1927(k)(2)(C). Section 1927(k)(2)(C) defines “insulin” as insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

v. The following medical supplies associated with the injection of Insulin: syringes, needles, alcohol swabs, and gauze.

vi. Vaccines licensed under Section 351 of the Public Health Services Act.

Drugs that do NOT meet the definition of Part D eligible will not be allowed for coverage under the Transition Process as they are statutorily excluded from Part D coverage will be defined as follows:

i. Drugs that are paid under prescribed and dispensed to an individual which are covered under Parts A or B (even if the person has declined to enroll in Parts A or B).

ii. Drugs or classes of drugs, which may be excluded from coverage or otherwise restricted under Section 1927(d)(2) or (d)(3), except for smoking cessation agents which will be covered.

iii. The Medicare Prescription Drug Benefit Manual Chapter 6 notes that section 1927(d)(2) defines the following drugs as drugs that may be subject to restrictions under Medicaid and not covered under Part D:

1. Agents when used for anorexia, weight loss, or weight gain.

2. Agents when used to promote fertility.

3. Agents when used for cosmetic purposes or hair growth.

4. Agents when used for the symptomatic relief of cough and colds.

5. Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

6. Nonprescription drugs.

7. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

8. Agents when used for the treatment of sexual or erectile dysfunction (ED).ED drugs will meet the definition of a Part D drug when prescribed for medically-accepted indications approved by the FDA other than sexual or erectile dysfunction.

iv. Section 1927(d)(3) gives the HHS Secretary to, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.

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, but 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 detail how to contact the 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 allow for a temporary fill of medication in order to meet the beneficiary's need 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.

Drug utilization management edits that are appropriate during a beneficiary's transition period include the following:

- Part A or B vs. Part D determinations
- FDA Non-matched NDCs
- Blocking of non-Part D drugs (excluded drugs)
- Safety utilization for Part D drugs (quantity limits at FDA maximum dosages)

CastiaRx will work with Plan Sponsors to perform routine auditing and quality assurance checks on the transition process to make all reasonable and best effort attempts 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 possibly rejected that should have been processed for a beneficiary under transition. Claims paid under the transitional benefit are also reviewed to ensure these claims are for appropriate transitional situations as well as tiering, days supply allowed and possible inappropriately paid transitional claims. The results of these reviews are reviewed for system parameter implementation.