

## **I. PURPOSE**

The purpose of the Policy and Procedure is to ensure necessary continuity of treatment and to provide adequate time and transition process to introduce the enrollee and their prescribing physician to the [Molina Healthcare] Formulary.

## **II. POLICY**

A. The primary objectives of [Molina Healthcare]'s Transition Policy and Procedure are:

- To provide procedures to address situations where a new enrollee initially presents at a participating pharmacy with a prescription medication that is not on [Molina Healthcare]'s formulary or has utilization management in order to accommodate the immediate needs of the beneficiary.
- To provide transition procedures to address the needs of current enrollees who have an immediate need for a formulary drug that has new and approved utilization management criteria (prior authorization, step therapy, quantity limits).
- To provide transition procedures to address the needs of current enrollees who have an immediate need of non-formulary drugs due to a change in level of care such as discharge from a hospital or skilled nursing facility.
- To provide transition procedures for newly eligible Medicare beneficiaries from other coverage.
- To provide transition procedures for members who switch from one plan to another after the beginning of the contract year.
- To define transition procedures to meet the unique needs of residents in Long Term Care facilities.

B. [Molina Healthcare] PBM has system capabilities that will allow for a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow [Molina Healthcare] 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.

- a. Systems capabilities exist to provide transition supplies at point-of-sale. Pharmacies are not required to either submit, or resubmit a Prior Authorization/Medical Certification Code (PAMC) or other TF-specific codes for a TF-eligible claim to adjudicate.

## **III. PROCEDURE**

### **A. Transition Issues**

#### a. All Enrollees

1. The transition policy applies to non-formulary drugs, which include: (1) Part D drugs that are not on [Molina Healthcare]'s formulary, and (2) Part D Drugs that are on a [Molina Healthcare]'s formulary but require prior authorization or step therapy under a [Molina Healthcare]'s utilization management rules. (3) Non-Part D drugs, required by Medicaid for the MMP plans or MMCP wrap benefit. The transition policy also applies to a brand-new prescription for a non-formulary drug if a distinction cannot be made between a brand-new prescription for a non-formulary drug and an ongoing prescription for a non-formulary drug

- at the point-of-sale. (4) Drugs that have an approved QL lower than the beneficiary's current dose.
2. [Molina Healthcare] will make its transition policy available to enrollees via a link from Medicare Prescription Drug Plan Finder to the [Molina Healthcare] web-site and include in pre- and post-enrollment marketing materials per CMS guidance.
  3. For current enrollees whose drugs are no longer on the [Molina Healthcare] formulary, [Molina Healthcare] will ensure a meaningful transition by either: (1) providing transition supplies of medications the same as the transition supplies required for new enrollees at the beginning of a new contract year; or (2) activating a transition process prior to the beginning of a new contract year.
  4. The member and provider must utilize the exceptions process, as defined in PD-20 "Medicare Part D Exceptions", to initiate a formulary exceptions or prior authorization to [Molina Healthcare] if they choose to continue the medication after the transition period. Alternatively, the member's pharmacy may contact [Molina Healthcare] by phone or fax to notify [Molina Healthcare] request for authorization.
  5. Prior authorization or exceptions request forms will be available to both enrollees and prescribing physicians via mail, fax, email, or [Molina Healthcare]'s web site.
  6. For all Prior Authorization/Exceptions requests submitted on behalf of newly-transitioning members, [Molina Healthcare] will make every effort to evaluate the reason a formulary therapeutic alternative may not be used.
  7. [Molina Healthcare] efforts may include (but is not limited to) speaking with the member's prescribing physician, primary care physician, and/or pharmacist to help the beneficiary satisfy utilization management requirements, switch to a formulary alternative, or initiate an exception
  8. [Molina Healthcare] will authorize network pharmacies to override step therapy and prior authorization system edits for transition supply prescriptions at point-of-sale (other than those in place to determine Part A or B vs Part D coverage, prevent coverage of non-Part D drugs and promote safe utilization of a Part D drug (e.g. quantity limits based on FDA maximum recommended dose, early refill edits).
  9. [Molina Healthcare] will work with its PBM to implement appropriate systems changes to achieve the goals of any additional new messaging approved through NCPDP to address clarifying information needed to adjudicate a Part D transition claim or other alternative approaches that achieve the goals intended for network pharmacy transition messaging at point of sale.
  10. If a member enrolls in [Molina Healthcare] with an effective enrollment date of either [November 1 or December 1], the transition policy will extend across the contract year for transition supplies of medication. Of note, a new member may also be eligible for a renewing member transition fill in the new calendar year.

11. [Molina Healthcare] will authorize a one-time emergency supply process to ensure the enrollees do not have a coverage gap while proceeding through the [Molina Healthcare]’s exception process.

a. New and Existing Members

1. [Molina Healthcare] will provide a temporary at least [31-day] fill (unless the prescription is written for less than a [31] day supply or the prescription is dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits based on approved product labeling, in which case [Molina Healthcare] will allow multiple fills to provide up to a total of [31] days of medication) in a retail setting or via home infusion, safety-net or I/T/U/ pharmacy any time during the first [90] days of member’s enrollment, beginning on the enrollee’s effective date of coverage. This includes new enrollees into our plan following the annual coordinated election period, newly eligible beneficiaries from other coverage and members who switch from one plan to another after the beginning of the contract year.

- a) *For IL only:* Non-Part D drugs, required by the Medicaid of Illinois for the MMP plans wrap benefit will have a [180-day] transition period
- b) *For SC only:* New members will have a [180-day] transition period for Part D medications and Medicaid wrap medications. Existing members will have a [90-day] transition period for both Part D and Medicaid wrap medications.

2. Existing members may be affected by situations where prescribed drug regimens in one care setting may not be included in the Part D formulary subsequent to change in level of care (LTC to acute care, acute care to home, home to LTC etc.).

- 3. Existing members currently receiving formulary drugs that have been removed from formulary or have newly added utilization management criteria i.e. step therapy and prior authorization are eligible for a transition supply. This includes current enrollees affected by negative formulary changes across contract years.
- 4. Existing members that have a drug that was previously approved for coverage under an exception will be granted a [31-day] transition fill once the exception expires.
- 5. The member and provider must utilize the exceptions process, as defined in PD-20 “Medicare Part D Exceptions”, to notify the plan of a transition situation.
- 6. [Molina Healthcare] will make arrangements to continue to provide necessary Part D drugs to enrollees and non-Part D drugs, as required by Medicaid, to MMP enrollees via an extension of the transition period, on a case-by-case basis, to the extent that their exception requests or appeals have not been processed by the end of the minimum transition period and until such time as a transition has been made (either through a switch to an appropriate formulary drug or a decision on an exception request).

7. The co-pay or cost-sharing for a temporary supply of drugs provided under the transition process will never exceed the statutory maximum co-payment amounts for low-income subsidy (LIS) eligible enrollees. For non-LIS eligible enrollees, [Molina Healthcare] will ensure that the co-pay or cost-sharing for a temporary supply of drugs provided under its transition process is based on one of its approved cost-sharing tiers and is consistent with co-pays or cost-sharing [Molina Healthcare] would charge for formulary drugs subject to utilization management edits provided during the transition that would apply once the utilization management criteria are met. For non-LIS enrollees, [Molina Healthcare] will ensure the same cost sharing for non-formulary Part D drugs is provided during the transition that would apply for non-formulary drugs approved through a formulary exception and 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.
8. During the transition period, point of sale claims at network pharmacies will override step therapy and prior authorization edits at point-of-sale by an automated process and a message will appear in the pharmacy screen describing the process as a “transition fill”.
9. If the transition supply is dispensed for less than the written amount due to a quantity limit edit, the transition supply can be refilled for up to a [31-day] supply (unless the quantity limit is based on safety limits established by the FDA or documented in peer reviewed medical literature or well-established clinical practice guidelines).
10. TF processing for Multi-Ingredient Compound (MIC) drugs is based on the formulary status of the entire claim. Topical MICs are considered Non-formulary and non-topical MICs are based on most expensive ingredient submitted. Only Non-formulary drugs will process under MIC TF rules. Step therapy protocols are bypassed for MIC drugs and these claims are paid outside of TF. QvT, daily dose and age edits may be bypassed for MIC drugs and claims paid outside of TF based on benefit design set-up. Since MICs are Non-formulary Drugs and generally covered only pursuant to an approved exception request, MIC drugs processed for TF are assigned the cost share applicable to the exception tier (i.e., the cost sharing applicable to Non-formulary Drugs approved pursuant to an exception request.)

Step 1: MIC adjudication determines the type of compound; determines if the MIC is a Part A or B or Part D drug. If the MIC is determined to be Part D eligible drug (no Part A or B ingredients and at least one Part D ingredient), then proceed to Step 2.

Step 2: Adjudication determines the formulary status of the Part D MIC claim based on benefit design; benefit setup determines if it is either formulary or Non-formulary.

- i. The plan has designated topical compounds as Non-formulary, therefore the entire claim is considered Non-formulary and TF will apply.
- ii. For Non Topical compounds, the plan bases the formulary status on the most expensive Part D ingredient:

If the most expensive ingredient is a formulary drug, then all Part D ingredients in the MIC pay at contracted rates.

If the most expensive ingredient is Non-formulary and is eligible for TF, then all Part D ingredients in the MIC pay as a TF. The TF letter refers to this prescription as a “compound” prescription.

If the most expensive ingredient is not eligible for TF, the entire MIC will reject / not pay as TF.

b. Long-term Care Members

1. [Molina Healthcare]’s transition procedure accounts for the unique needs of residents of LTC facilities and recognizes that LTC residents are likely to be receiving multiple medications for which simultaneous changes could significantly impact the condition of the enrollee.
2. [Molina Healthcare] will provide a temporary at least [31-day] fill (unless the prescription is written for less than a [31] day supply or the prescription is dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits based on approved product labeling, in which case [Molina Healthcare] will allow multiple fills to provide up to a total of [31] days of medication) in an LTC setting any time during the first [90] days of member’s enrollment, beginning on the enrollee’s effective date of coverage.
3. After the [90] day transition period has expired, [Molina Healthcare] will authorize a [31-day] emergency supply of non-formulary medications (unless prescription is indicated for less than [31] days) while an exception or prior authorization is requested. On a case-by-case basis, [Molina Healthcare] will make arrangements to provide necessary medications to an enrollee by extending the transition period if the enrollee’s exception request or appeal has not been processed by the end of the minimum transition period.
4. If a member enrolls in [Molina Healthcare] with an effective enrollment date of either [November 1 or December 1], the transition policy will extend across the contract year for transition supplies of medication.
5. All contracted LTC facilities will be notified of the following terms:
  - [Molina Healthcare] will cover the full cost of the medication (at contracted rates) during such time that a Prior Authorization request is reviewed for the member, and
  - [Molina Healthcare] requires LTC facilities to submit a Prior Authorization if and when it is required for the medication to be dispensed.
6. If the LTC facility, physician, or “appointed representative” fails to submit a Prior Authorization as required, [Molina Healthcare] will not pay for medication dispensed outside of this [90 day] period.

7. If the LTC (and its preferred pharmacy) are not part of the network, either by choice or by not meeting conditions of participation, [Molina Healthcare] will pay for the same medication supply at LTC pharmacy network rates.

#### IV. NOTIFICATIONS

- A. Within [three (3)] business days of adjudication of a temporary fill or within [3] business days after the adjudication of the first temporary fill for a long-term care resident dispensed multiple supplies of a Part D drug in increments of [14-days-or-less], [Molina Healthcare] via PBM will send the enrollee a written notification via U.S. first class mail. (*refer to Attachment I and II*):
  - a. The transition supply provided is temporary and may not be refilled unless a formulary exception is approved.
  - b. Instructions for the enrollee to correspond with [Molina Healthcare] and his/her provider to identify appropriate therapeutic alternatives on [Molina Healthcare]'s formulary.
  - c. An explanation of the enrollee's right to request a formulary exception.
  - d. [Molina Healthcare] procedures for requesting a formulary exception.
  - e. [Molina Healthcare] will send written notice via U.S. first class mail to enrollee within [three] business days of adjudication of a temporary transition fill. The notice must include (1) an explanation of the temporary nature of the transition supply an enrollee has received (2) instructions for working with the plan sponsor and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on the plan's formulary (3) an explanation of the enrollee's right to request a formulary exception and (4) a description of the procedures for requesting a formulary exception. 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, the written notice will be provided within [3] business days after adjudication of the first temporary fill. [Molina Healthcare] will use the CMS model Transition Notice via the file-and-use process or submit a non-model Transition Notice to CMS for marketing review subject to a [45-day review]. [Molina Healthcare] will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice.

#### V. REVIEW OF TRANSITION-RELATED EXCEPTIONS REQUEST

- A. Transition-related exceptions and appeals will follow [Molina Healthcare]'s Exceptions and Appeals Policy and Procedures defined in PD-20, "Medicare Part D Exceptions".
- B. For transition members, particular attention will be given when reviewing Prior Authorization requests.
- C. If the Reviewer determines that a change in medication to a formulary alternative would jeopardize the safety and well-being of the member, an approval will be given even if specific criteria for that medication are not met.

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