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AUTHORITIES/REFERENCES

Federal

Title

o 42 CFR § 423.120(b)(3)

Chief Medical Officer

- Medicare Prescription Drug Benefit Manual, Chapter 6 Part D Drugs and Formulary Requirements
- o MA-PD Soliciation
- o CMS Transition Process Requirements for Part D Sponsors, April 2007
- o CMS Medicare MA-PD Sponsor Par D Audit Guide Version 1.0, April 10, 2006

	HISTORY
Revision Date	Description of Revision
5/28/2025	Policy creation
07/16/2025	Policy Revision- CMS Review
07/18/2025	Policy Revision- CMS Review

I. OVERVIEW



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Community Health Plan of Imperial Valley's ("CHPIV" or the "Plan") is responsible for ensuring compliance with established CMS transition requirements.

- 1. To ensure access to needed drugs for:
 - a. New enrollees transitioning into Community Health Plan of Imperial Valley (CHPIV) following the annual coordinated election period,
 - b. Newly eligible beneficiaries transitioning from other coverage,
 - c. Individuals transitioning from one plan to another after the start of a contract year,
 - d. Current enrollees affected by negative formulary changes across contract years; and
 - e. Enrollees residing in long-term care (LTC) facilities.

CHPIV transition policy will apply to non-formulary drugs, meaning both (1) drugs that are not on the plan's formulary and (2) drugs that are on the plan's formulary but require prior authorization or step therapy, or that have an approved quantity limit lower than the MEMBER'S current dose, under CHPIV's utilization management rules. CHPIV's policy addresses procedures for review of non-formulary drug requests, and when appropriate, a process for switching new MMP enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.

In accordance with CMS requirements, CHPIV will ensure that drugs excluded from Part D coverage due to Medicare statute are not eligible through the transition process. However, to the extent that CHPIV covers certain excluded drugs under an Enhanced benefit, those drugs should be treated the same as Part D for the purposes of the transition process.

2. To accommodate the immediate needs of an enrollee, as well as to allow CHPIV and/or the enrollee sufficient time to work with the prescriber to switch to a therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on reasons of medical necessity.

II. POLICY

- 1. CHPIV will ensure to have an appropriate transition process in place for new and existing enrollees who are prescribed Part D drugs that are not on CHPIV's integrated formulary (non-formulary drugs), drugs previously approved for coverage under an exception once the exception expires, and drugs that are on the integrated formulary but require prior authorization or step therapy (formulary with utilization management rules), or that have an approved quantity limit lower than the beneficiary's current dose, and are not otherwise excluded from coverage.
- 2. CHPIV's policy and process will be consistent with written policy guidelines and other instructions from Centers for Medicare and Medicaid Services (CMS).
- 3. This policy applies to the following CHPIV MEMBERS:





- a. new enrollees into prescription drug plans on January 1, of each year following the annual coordinated election period;
- b. newly eligible beneficiaries transitioned from other coverage;
- c. individuals transitioning from one plan to another after January 1;
- d. enrollees residing in long-term care (LTC) facilities;
- e. and enrollees whose drugs will be affected by negative formulary changes across contract years.
- 4. CHPIV will ensure to expedite transitions to formulary drugs for enrollees who change treatment settings due to changes in level of care.
- 5. CHPIV will ensure to provide a temporary supply fill anytime during the first 90 days of a beneficiary's enrollment from the effective date of coverage, including long-term care facility resident enrollees. CHPIV will provide a temporary 31-day fill when a beneficiary presents at a retail pharmacy or Long Term Care (LTC) pharmacy to request a refill of a non-formulary drug, drugs previously approved for coverage under an exception once the exception expires, or a formulary drug requiring prior authorization or step therapy or that have an approved quantity limit lower than the beneficiary's current dose under CHPIV's utilization management rules. If the enrollee presents with a prescription written for less than a 31-day supply, CHPIV will allow multiple fills to provide up to a 31-day supply of medication.
- 6. CHPIV, through its Pharmacy Benefit Manager (PBM), has established on-line edits associated with temporary supplies of non-formulary drugs at the point of sale to ensure that the beneficiary is able to leave the pharmacy with a sufficient quantity of medication. Only the following drug utilization management edits may apply during a beneficiary's transition period:
 - a. Edits to help determine Part A or B vs. Part D coverage
 - b. Edits to help determine Part D drugs and products coverage and to prevent coverage of non-part D (i.e. excluded drugs)
 - c. Edits to promote safe utilization of a Part D drug (e.g., quantity limits based upon FDA maximum recommended daily dose; early refill edits).
- 7. If a utilization management edit is overridden at the point of sale for transition purposes only, but not permanently, the beneficiary must be notified so that he or she can begin the exception process if necessary.
- 8. CHPIV may implement quantity limits for safety purposes or drug utilization edits that are based upon approved product labeling during a beneficiary's transition period. To the extent that the prescription is dispensed for less than the written amount due to a plan edit, CHPIV will provide refills for that transition supply (up to a 31-day supply in a retail setting and a 31-day supply in a long-term care setting).
- 9. These edits are subject to exceptions and appeals and CHPIV will expeditiously process such exception requests so that beneficiaries will not experience unintended interruptions in medically





necessary Part D and and/or inappropriately pay additional cost-sharing associated with multiple fills of lesser quantities when the originally prescribed doses of Part D drugs are medically necessary.

- 10. If a distinction cannot be made at the pharmacy whether the beneficiary is presenting with a refill of on-going medication therapy vs. a new prescription for a non-formulary drug at the point of sale, CHPIV will ensure to apply all transition process standards specified by CMS.
- 11. CHPIV will ensure to provide enrollees with appropriate notice regarding their transition process within three (3) business days of providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on the formulary but require prior authorization or step therapy under CHPIV's utilization management rules or that have an approved quantity limit lower than the beneficiary's current dose). For long term care residents dispensed multiple supplies of a Part D drug in increments of 14 days or less, the written notice will be provided within three (3) business days after adjudication of the first temporary transition fill. CHPIV uses the CMS model Transition Notice via the file-and-use process or will submit a non-model Transition Notice to CMS for marketing review subject to a 45-day review. CHPIV does not delegate the sending of required transition fill notices to network long term care pharmacies. CHPIV will ensure to send a written notice, via U.S. first class mail, to each enrollee who receives a transition fill.

The notice will include the following elements:

- a) An explanation of the temporary nature of the transition supply that the enrollee received;
- b) Instructions for working with CHPIV and the enrollee's prescriber to satisfy utilization management requirements or to identify appropriate therapeutic alternatives that are on CHPIV's formulary;
- c) An explanation of the enrollee's right to request a formulary exception;
- d) A description of the procedures for requesting a formulary exception;
- e) Reason for the transition fill; and
- f) Alternate formulary drugs.

CHPIV will ensure that reasonable efforts are made to notify prescribers of affected enrollees who receive a transition notice. Prescribers receive a written and faxed notification when affected enrollees receive a transition notice.

- 12. CHPIV will ensure to make authorization or exception request forms available upon request to both enrollees and prescribing physicians via a variety of mechanisms including mail, fax, e-mail, and CHPIV's web site.
- 13. CHPIV will ensure to make general information about the transition process available to beneficiaries via a link from the Medicare Prescription Drug Plan Finder to CHPIV's web site and will include information about the policy in pre- and post-enrollment marketing materials as directed by CMS.
- 14. For a new enrollee in the LTC setting, CHPIV will ensure to provide a 31-day fill consistent with the applicable dispensing increment in the long-term care setting (unless the enrollee presents with a prescription written for less), with refills provided if needed during the first 90 days of a beneficiary's enrollment. However, to the extent that an enrollee in an LTC is outside his or her 90-day transition period, CHPIV will provide an emergency supply of non-formulary drugs (or those on formulary with utilization management rules) while an exception or prior authorization is being



- requested. These emergency fills will be for at least 31 days of medication, unless the prescription is written for less than 31 days.
- 15. For unplanned transitions, e.g., enrollee discharged from the hospital to an LTC or home, CHPIV will ensure to make coverage determinations and re-determinations as expeditiously as the enrollee's health condition requires. Enrollees involved in unplanned transitions will be provided an emergency supply of non-formulary drugs, including Part D formulary drugs requiring utilization management.
- 16. CHPIV will ensure to not reject claims based on early refill edits when an enrollee is admitted or discharged from an LTC facility. This means that early refill edits are not used to limit appropriate and necessary access to their Part D benefit, and such enrollees are allowed to access a refill upon admission or discharge.
- 17. For current enrollees whose drugs are no longer on CHPIV's formulary, or remain on the formulary but to which new prior authorization or step therapy restrictions are applied, CHPIV will ensure to provide a transition process consistent with the transition process required for new enrollees beginning in the new contract year.
- 18. If a beneficiary enroll in a plan with an effective enrollment date of either November 1 or December 1 and need access to a transition supply, CHPIV will extend the transition policy across contract years.

III. PROCEDURE

- 1. CHPIV delegates the Medicare transition process to its Subcontractor, Community Health Group.
- 2. Delegation Oversight
 - A. CHPIV shall provide oversight and continually assess the delegated functions, responsibilities, processes, and performance of Community Health Group. CHPIV ensures Community Health Group's compliance with regulatory and contractual requirements through the following activities which are detailed in CHPIV Policy CMP-002: Delegation Oversight Policy and Procedure:
 - a. Ongoing monitoring
 - b. Performance reviews
 - c. Data analysis
 - d. Utilization of benchmarks, if available
 - e. Annual desktop and on-site audits
- 3. The PBM will apply the transition process to all non-formulary Part D drugs and integrated formulary drugs that have step therapy, quantity limits or prior authorization as part of CHPIV's utilization management rules. During transition, MEMBERS will be allowed fills of these drugs automatically, at the point of sale, by establishing a point of service (POS) transition edit. The number of transition days and quantity day supply for both retail and long term care settings will be set. Claims for drugs allowed through the transition process will be marked in such a way that allows them to be tracked and reported to beneficiaries and to CMS.
- 4. Notification will happen in two ways:



- a. Point of Sale notification: Shall go to the pharmacy at time of adjudication with messaging that may be passed to the MEMBER regarding the status of the particular non-formulary drug or drug with utilization management rules. The transition messaging goes to pharmacies in a retail setting (including home infusion, safety-net and Indian Tribal Union) as well as pharmacies in an LTC setting. The transition messaging is passed in the proper messaging fields as specified by CMS and NCPDP standards.
- b. Daily File extract: the PBM will supply CHPIV with a daily file of any MEMBERS with a transition claim and provided with formulary alternate therapy options. CHPIV will ensure to notify the MEMBER and/or provider with these options and/or information on pursuing a medical exception request as described above. CHPIV also contracts with a print vendor. The print vendor receives the transition care notification file from the PBM and facilitates the fulfillment process of MEMBER notification.
- 5. For low-income subsidy (LIS) eligible MEMBERS, the cost-sharing amount applied during claims adjudication does not exceed the statutory maximum co-payment amounts. For non-LIS eligible MEMBERS, CHPIV will ensure that cost-sharing for a temporary supply of drugs provided under the transition process is consistent with approved cost-sharing tiers and is consistent with cost-sharing for non-formulary drugs approved under a coverage 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.
- 6. Drugs dispensed during the transitional period will be reported as covered integrated formulary drugs with appropriate plan and beneficiary cost sharing amounts on the prescription drug event (PDE).
- 7. Enrollees transitioning to CHPIV on a drug within the six (6) therapeutic classes listed below will be allowed continued coverage of therapy for the duration of treatment, up to the full duration of active enrollment in CHPIV Utilization management restrictions (PA, step therapy and non-formulary status), which may apply to new patients naive to therapy, will not apply to enrollees transitioning to the MMP plan on agents within these key categories:
 - a. Antidepressants
 - b. Antipsychotics
 - c. Anticonvulsants
 - d. Antineoplastics
 - e. Immunosuppressants (for prophylaxis of organ transplant rejection)
 - f. Antiretroviral

For new MEMBERS, protected class drug logic will always override transition logic to process the claim. Additionally for new MEMBERS, a 120-day transition period from their MEMBER start date is provided.

8. CHPIV's PBM will follow an overall transition plan for Part D beneficiaries. A component will include the exceptions process. The PBM's exceptions process will integrate with the overall transition plan for Part D beneficiaries in the following areas:



- a. PBM's exceptions process will complement other processes and strategies to support the overall transition plan. The exception process will follow the guidelines set forth by the transition plan when applicable.
- b. When evaluating an exception request for transitioning beneficiaries from a non-formulary drug, CHPIV's medical review process will consider the clinical aspects of the drug, including any risks involved in switching to therapeutically appropriate formulary alternatives.
- c. The exception policy includes a process for switching new Part D plan enrollees to therapeutically appropriate formulary alternatives failing an affirmative medical necessity determination.
 - 1. The Prescriber Transition Letter provides prescribers with instructions to access the Plan's formulary, as well as instructions on additional information to provide in a supporting statement for an exception request.
 - 2. When evaluating an exception request for transitioning MEMBERS, the Plan's exception evaluation process includes a medical review that considers the clinical aspects of the drug, including any risks involved in switching.
 - a. This medical review process includes the following steps:
 - i. Outreach is made to the provider to offer therapeutically appropriate formulary alternatives.
 - ii. This provides the prescriber an opportunity to switch the MEMBER to a covered formulary medication.
 - iii. If the prescriber feels the formulary alternatives are not clinically appropriate for the MEMBER, they can provide attestation that the alternatives would not be as effective or would cause adverse effects which would lead to an approval of the requested medication.
- 9. Transition Extension: CHPIV will ensure to 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, to the extent that an exception request or appeal has 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).
- 10. Transition Across Contract Years: For current enrollees whose drugs will be affected by negative formulary changes in the upcoming year, CHPIV will effectuate a meaningful transition by either: 1) providing a transition process at the start of the new contract year or 2) effectuating a transition prior to the start of the new contract year. The PBM's Point of Sale (POS) logic is able to accommodate option #1 by allowing current MEMBERS to access transition supplies at the point-of-sale when their claims history from the previous calendar year contains an approved claim for the same drug that the MEMBER is attempting to fill through the transition and the drug is considered a negative change from one plan year to the next. To



accomplish this, POS will look back 180 days for Part D claims in the MEMBER'S claim history that were approved prior to January 1 of the new plan year, and that have the same HICL value as the transition claim. Additionally, if a brand medication is being filled under transition, the previous claim must also be brand (based on the NSDE marketing status). If a generic medication is being filled under transition, the previous claim can be either brand or generic (based on NSDE marketing status). Negative changes are changes to a formulary that result in a potential reduction in benefit to MEMBERS. These changes can be associated with removing the covered Part D drug from the formulary, changing its preferred or tiered cost-sharing status, or adding utilization management. The transition across contract years is applicable to all drugs associated to mid-year and across plan-year negative changes.

- Since CHPIV has adopted a standard PBM formulary for its Medicare beneficiaries, the PBM's Pharmacy and Therapeutics (P&T) Committee (vs. CHPIV's P&T Committee) maintains a role in the transition process in the following areas:
 - a. The PBM's P&T Committee reviews and recommends all PBM formulary step therapy and prior authorization guidelines for clinical considerations; and
 - b. The PBM's P&T Committee reviews and recommends procedures for medical review of non-formulary drug requests, including the PBM's exception process.
- 11. The majority of the membership of the PBM's P&T Committee used to develop and review the formulary submission for each benefit year is comprised of practicing physicians and/or practicing pharmacists. Membership includes at least one practicing physician and at least one practicing pharmacist who are experts in the care of the elderly or disabled persons and at least one practicing physician and at least one practicing pharmacist who are both free of conflict with respect to Community Health Group and pharmaceutical manufacturers.
- 12. CHPIV will ensure that the parameters of the transition plan are accurately reflected in the PBM's POS system. Additionally, CHPIV will validate that the PBM's customer service notes and documentation accurately reflect CHPIV's plan and that the PBM customer service and prior authorization staff are trained on CHPIV's transition plan.
- 13. CHPIV will ensure to regularly conduct training with its internal customer service and case management staff to ensure that as they work with enrollees on their individual care plans or when transitioning MEMBERS between treatment settings, staff is aware of the transition policy. This will provide staff with the opportunity to proactively work with enrollees and CHPIV's pharmacy services staff to facilitate transition to a formulary drug, where applicable
- 14. Until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, CHPIV will promptly implement either:
 - a. Appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim, or
 - b. Alternative approaches that achieve the goals intended in the messaging guidance.



- 15. CHPIV works closely with its PBM to ensure accurate implementation within the claims adjudication system. The following is an implementation statement that is included in the PBM policy, "Transition Process Requirements for Medicare Part D".
 - a. Claims Adjudication System: MedImpact has systems capabilities that allow MedImpact to provide a temporary supply of non-formulary Part D drugs in order to accommodate the immediate needs of an enrollee, as well as to allow the plan and/or the enrollee sufficient time to work with the prescriber to make an appropriate switch to the therapeutically equivalent medication or the completion of an exception request to maintain coverage of an existing drug based on medical necessity reasons.
 - a) Pharmacy Notification at Point-of-Sale: Until such time as alternative transaction coding is implemented in new version of the HIPAA standard, MedImpact will promptly implement either:
 - Appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim (see the 5.1 Editorial Document), or
- 16. Alternative approaches that achieve the goals intended in the messaging guidance.
 - b. Edits During Transition: During an enrollee's transition period, the only edits that are enforced by MedImpact's claims adjudication system are:
 - 1) Edits to help determine Part A or B vs. Part D coverage,
 - 2) Edits to help determine Part D drugs and products coverage to help prevent Coverage of non-Part D drugs (i.e., excluded drugs), and
 - 3) Edits to help promote safe utilization of a Part D drug (i.e., quantity limits based on FDA maximum recommended daily dose, early refill edits.

MedImpact will ensure that the transition policy provides refills for transition prescriptions dispensed for less than the written amount due to quantity limits for safety purposes or drug utilization edits that are based on approved product labeling.

d. Pharmacy Overrides at Point-of-Sale: During the MEMBER'S transition period, all edits (with the exception of those outlined in Part C above) associated with non-formulary drugs are automatically overridden by MedImpact's claims adjudication system at the point-of-sale.

MedImpact will ensure that pharmacies can override step therapy and prior authorization edits – other than those that are in place to determine Part A or B vs. Part D coverage, determine Part D coverage and 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) – during transition at point-of-sale.

Pharmacies can also contact MedImpact's Pharmacy Help Desk directly for immediate assistance with point-of-sale overrides, MedImpact can also accommodate overrides at point-of-sale for emergency fills as described in section 1.6.





IV. DEFINITIONS

Whenever a word or term appears capitalized in this policy and procedure, the reader should refer to the "Definitions" below.

TERM	DEFINITION
Centers for Medicare & Medicaid Services (CMS)	The federal agency responsible for the administration of Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and the Health Insurance Marketplace. CMS develops and enforces regulations, oversees health care quality standards, and ensures compliance for public health insurance programs nationwide.
Medically Necessary/Medical Necessity	Means all Covered Services that are reasonable and necessary to protect life, prevent illness or disability, alleviate severe pain through the diagnosis or treatment of disease, illness or injury, achieve age-appropriate growth and development, and attain, maintain, or regain functional capacity per Title 22 CCR Section 51303(a) and 42 CFR 438.210(a)(5). When determining the Medical Necessity of Covered Services for a Medi-Cal beneficiary under the age of 21, "Medical Necessity" is expanded to include the standards set forth in 42 USC Section 1396d(r), and W & I Code Section 14132 (v). For individuals under 21 years of age, EPSDT service is considered medically necessary or a medical necessity when it is necessary to correct or ameliorate defects and physical and mental illnesses and conditions that are discovered by screening services. A service need not cure a condition in order to be covered under EPSDT. Services that maintain or improve the child's current health condition are also covered under EPSDT because they "ameliorate" a condition. Maintenance services are defined as services that sustain or support rather than those that cure or improve health problems. Services are covered when they prevent a condition from worsening or prevent development of additional health problems. The common definition of "ameliorate" is to "make more tolerable". Additional services must be provided if determined to be medically necessary for an individual child.
Member	A beneficiary enrolled in a CHPIV program.
Provider	Individual or entity that is engaged in the delivery of services, or ordering or referring for those services, and is licensed or certified to do so.
Subcontractor	An individual or entity that has a subcontract with the MCP that relates directly or indirectly to the performance of the MCP's obligations under



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the contract with DHCS. A network provider is not a subcontractor by virtue of the network provider agreement, as per 42 CFR § 438.2.