| POLICY AND PROCEDURE | |
|---|---|
| **Title:**<br>Outpatient Drugs Part B versus Part D | |
| **Primary policy owner:**<br>Pharmacy | **Policy #:**<br>PH43 |
| **Impacted/Secondary policy owner:** Select the department(s) that are responsible for compliance with all, or a portion of the policy or procedure as outlined | |
| 1) ☐All Departments<br>2) ☐Behavioral Health & Social Services (BH/SS)<br>3) ☐ Benefits Administration (BA)<br>4) ☐ Case Management (CM)<br>5) ☐ Claims (CLMS)<br>6) ☐ Community Marketplace & Member Engagement (MAR)<br>7) ☐ Compliance (CMP/HPA)<br>8) ☐ Configuration (CFG)<br>9) ☐ Provider Contracting (CONT)<br>10) ☐ Cultural & Linguistics (CL)<br>11) ☐ Customer Service (CS) | 12) ☐ Facilities (FAC)<br>13) ☐ Finance (FIN)<br>14) ☐ Human Resources (HR)<br>15) ☐ Information Technology / Core Systems (IT)<br>16) ☒ Pharmacy (PH)<br>17) ☐ Provider Networks (PRO)<br>18) ☐ QI Health Equity (GRV/HE/HEQ/PHM/QM)<br>19) ☐ Utilization Management (UM)<br>20) ☐ Procurement (PRM)<br>21) ☐ Administration (SAF/BC/EM)<br>22) ☐ Medical Management (MM) |
| **Product Type:**<br>☐Medi-Cal<br>☒D-SNP | **Supersedes Policy Number:**<br>*NA* |

## I. PURPOSE

To ensure Health Plan of San Joaquin and Mountain Valley Health Plan ("Health Plan") is in compliance with all contractual requirements, applicable federal and state laws, and regulations for responding, preventing, reviewing, and investigating all reported and identified non-

compliance. Health Plan Workforce and Delegates appropriately adjudicate outpatient Part D and Part B medications in compliance with federal and state regulations and other program requirements.

## II. POLICY

A. Health Plan must identify and appropriately process claims for Part D and Part B medications according to criteria established by Center for Medicare and Medicaid Services (CMS).

B. Health Plan must abide by the definition of a Part D drug as listed in Title XVIII of the Social Security Act (Act) and in the regulations (42 CFR §423.100), which lists among other requirements:
   1. The drug must be approved by the Food and Drug Administration (FDA) and recognized as "Rx only" on its label per section 503(b)(4) of the Federal Food, Drug, and Cosmetic (FD&C) Act.
   2. The drug must not be excluded from coverage or otherwise restricted under section 1927(d)(2) of Act.
   3. The drug must not be eligible for coverage under Part A or Part B.

C. Health Plan must use CMS definition for Part B drugs to proactively identify outpatient Part B medications and not cover them as part D. Generally, outpatient Part B medications are those furnished "incident" to a physician service for drugs that are "Not Usually Self-Administered By the Patient."

D. For medications that could be either covered under Part B or Part D, depending on the circumstances, Health Plan must make every effort to correctly identify the proper coverage. (See details in the Procedure section).

E. Health Plan must be on the lookout for any new guidance from CMS and update its procedures accordingly.

F. Health Plan must ensure that all downstream entities follow the latest CMS regulations regarding Part B versus Part D medication processing.

## III. PROCEDURE

A. The Pharmacy Benefits Manager (PBM) provides Health Plan, annually, its current policies and procedures about Part D versus Part B claim determination at the point of sale and include all the latest requirements from CMS.

B. The PBM provides Health Plan its Pre-processing Drug Lists (PPDLs) that identify, proactively, medications that could be covered either under Part B or Part D.
    1. "Always Part B" are drugs that should be billed under Part B.
    2. "Part B vs Part D" drugs could be Part B or Part D depending on the circumstance or indication of their use. They shall generally require a determination to adjudicate appropriately and may be rejected at the point-of-sale (POS).
    Note: Some of the cases are identified in this Procedure section, with the understanding that not all scenarios can be covered and that the PBM shall ensure all CMS requirements in Part D versus Part B determination are met.

C. For rejecting claims awaiting Part D versus Part B determination, the PBM allows a payment determination prior authorization request to be initiated by the pharmacy if they have sufficient information (such as diagnosis information) to correctly assign payment to Part B or Part D.

Nebulized Inhalation Drugs

A. Inhalation Drugs used by a member with a nebulizer at home shall be covered under Part B.

B. To ensure appropriate claim adjudication, the PBM uses a patient residence code on a pharmacy claim to determine when such inhalation may be covered under Part D.
    1. Residence code of "0" or "1" are considered ambulatory (home).
    2. Residence code of "3" or "9" are Long Term Care Facilities.

Oral Anti-Cancer Drugs and Oral Anti-Emetics

A. If used for cancer, certain oral chemotherapy agents for which there is an infusible version of the drug shall be covered under Part B.

B. The PBM uses step therapy to look for approved history of claims for qualified predefined list of drugs to identify possible alternate diagnoses (example: Methotrexate and cyclophosphamide for the diagnosis of arthritis). If none is found, the claim is rejected and await Part B versus Part D determination.
C. Oral anti-emetics used in cancer treatment as a full replacement for intravenous treatment within 48 hours of cancer treatment is covered under Part B. Such drugs dispensed for use after the 48-hour period, or any oral anti-emetic prescribed for conditions other than the effects of cancer treatment, are adjudicated as Part D drugs.

Immunosuppressive Therapy for a Transplant Covered under Medicare

A. Immunosuppressive drug therapy following a Medicare covered organ transplant is covered under Part B.
B. Health Plan identifies transplant patients several ways:
    1. Medicare Advantage and Prescription Drug System (MARx): Contains Medicare entitlement dates and renal (kidney) transplant dates.
    2. Additional Beneficiary Information Initiatives (ABII) Portal: Medicare Covered Transplant Beneficiaries File – when notified from CMS.
C. The PBM flags the member as having an active transplant attribute.
    1. The PBM shall have a PPDL for FDA approved immunosuppressive drugs and shall adjudicate the claims as Part B when the transplant attribute is present.
    2. The claim shall reject, at the POS, for Part B versus Part D determination if the transplant attribute is absent.
D. The PBM provides Health Plan with retrospective reports of all the immunosuppressive drug claims that processed as Part D for Health Plan's review to ensure that they processed appropriately.

ESRD Claims

A. Health Plan does not cover, under Part D, dugs or biologics utilized by the member in an End Stage Renal Disease (ESRD) facility and covered under Medicare Part B per diem payment.

B. Health Plan receives, from CMS, a Transaction Reply Code (TRC) informing that a member has ESRD via the Daily Transaction Reply Report (DTRR). Health Plan shall utilize segment 08 within the PBM type 24 (Member Attribute Load file) to create a member attribute record.
C. The PBM has a PPDL for "ESRD Always" medications and shall reject them at the POS when the member is flagged as an ESRD patient. These medications include:
    1. Access Management: Drugs used to ensure access by removing clots from grafts, reverse anticoagulation if too much medication is given, and provide anesthetic for access placement.
    2. Anemia management: Drugs used to stimulate red blood cell production and/or treat, or prevent, anemia. This category includes Erythropoietin Stimulating Agents (ESAs) as well as iron.
    3. Bone and Mineral metabolism: Drugs used to prevent/treat bone disease, secondary to dialysis. This category includes phosphate binders and calcimimetics.
    4. Cellular Management: Drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.
D. The PBM has a PPDL for "ESRD Maybe" medications that could be covered as Part B if used for the treatment of ESRD. If not used for ESRD, the medication shall be payable under Part D.
    1. Antiemetics.
    2. Anti-infectives.
    3. Anti-pruritics.
    4. Anxiolytics.
    5. Excess fluid management.
    6. Fluid and Electrolyte Management including volume expanders.
    7. Pain Management.
E. Health Plan performs a retrospective review of claims for ESRD members to determine proper coverage.
    1. Health Plan validates the date the member was identified as an ESRD patient.

2. Health Plan reviews and validates that the "ESRD May Apply" drugs are appropriately adjudicating as Part D.
    i. Health Plan reviews claim details such as prescriber/dispensing pharmacy and contact ESRD providers/ prescribers, as needed, to verify that the medication is not used for the treatment of ESRD and the claim paid appropriately under Medicare Part D.
    ii. If a claim is identified as inappropriately paid under Part D, Health Plan communicates with the PBM immediately to exclude the Prescription Drug Event (PDE) record and works with the dialysis facility to recover the amount in question.
    iii. All reviews and related PBM communication shall have written documentation of the issue, follow-up, and resolution.

## IV. ATTACHMENT(S)

A. Glossary of Terms Link

## V. REFERENCES

A. Federal Food, Drug, and Cosmetic (FD&C) Act 503(b)(4)
B. Social Security Act Titles XVIII
C. Definition of Part D drug: 42 CFR §423.100
B. Part B versus D Coverage Policy https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf
C. Part B covered medications https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf
D. Medicare Benefit Policy Manual, Chapter 15 § 50.2 http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf
E. CMS Memo December 2024 - Inclusion of Oral-Only Drugs in the End-Stage Renal Disease (ESRD)Prospective Payment System (PPS) Bundled Payment beginning January 1, 2025 https://www.federalregister.gov/documents/2024/11/12/2024-

25486/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis

G. Analysis of Prescription Drug Event Records for Nebulizer Drugs Used with an item of Durable Medical Equipment. User Story 216233
H. State Medicaid Agency Contract (SMAC)
I. Health Plan Contract with Centers for Medicare & Medicaid Services (CMS)

## VI. REVISION HISTORY

| Version* | Revision Summary | Date |
|---|---|---|
| 001 | | |
| 002 | | |
| 003 | | |
| 004 | | |
| **Initial Effective Date: 09/24/2025** | | |
| **Published Date:09/29/2025** | | |

## VII. Committee Review and Approval To Be Completed by Compliance

| Committee Name | Version | Date |
|---|---|---|
| Compliance Committee | 001 | 09/24/2025 |
| • Privacy & Security Oversight Committee | | |
| • Program Integrity Committee | | |
| • Audits & Oversight Committee | | |
| • Policy Review Committee | | |
| Quality Improvement Health Equity Committee (QIHEC) | | |
| • Quality Operations Committee | | |
| • Grievance Committee | | |

## VIII. REGULATORY AGENCY APPROVALS

| Department | Reviewer | Version | Date |
|---|---|---|---|
| Department of Healthcare Services (DHCS) | | | |
| Department of Managed Care (DMHC) | | | |

## IX. *Approval signature**

| Signature | Name<br>Title | Date |
|---|---|---|
| | PRC Chairperson | |
| | Policy Owner | |
| | Department Executive | |
| | Chief Executive Officer | |

*Signatures are on file, will not be on the published copy