KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Part B Vs. Part D Coverage Determination	**Policy #**	13.29-P
Policy Owner	Pharmacy	**Original Effective Date**	01/01/2026
Revision Effective Date		**Approval Date**	1/22/2026
Line of Business	☐ Medi-Cal ☒ Medicare ☐ Corporate		

I. PURPOSE

The purpose of this document is to describe the Medicare Coverage Determination (CD) policy and procedures for Kern Health Systems (KHS) Pharmacy staff to help ensure compliance with all applicable federal and state laws and Centers for Medicare and Medicaid Services (CMS) requirements when a drug may be available under Part B or Part D.

II. POLICY

KHS and/or its Pharmacy Benefit Manager (PBM) must ensure that drugs for which coverage may be available under Part B or Part D, as it is being prescribed or administered to the Member, are provided under the correct benefit coverage. This is the policy of KHS to establish a standard for fully addressing and responding timely to these CD requests.

III. DEFINITIONS

TERMS	DEFINITIONS
Appeal	As defined at 42 Code of Federal Regulations (CFR) §422.561 and §423.560, the procedures that deal with the review of adverse initial determinations made by the plan on health care services or benefits under Part C or D the enrollee believes he or she is entitled to receive, including a delay in providing, arranging for, or approving the health care services or drug coverage (when a delay would adversely affect the health of the enrollee) or on any amounts the enrollee must pay for a service or drug as defined in 42 CFR §422.566(b) and §423.566(b). These appeal procedures include a plan reconsideration or redetermination (also referred to as a level one (1) appeal), a reconsideration by an independent review entity (IRE), adjudication by an Administrative Law Judge (ALJ) or attorney adjudicator, review by the Medicare Appeals Council

	(Council), and judicial review.
Appointed Representative	An individual either named by an enrollee including his/her prescribing physician or authorized under State or other applicable law to act on behalf of the enrollee. The Appointed Representative form is found on the KHS website.
Cash Purchase	A Member's purchase of a covered drug without using their KHS benefits.
CMS	The federal agency within the Department of Health and Human Services that administers the Medicare program and oversees all Medicare Advantage Organizations.
Controlled Medication	A prescription drug that is regulated by the Drug Enforcement Administration (DEA) based on its currently accepted medical use in treatment in the United States, its relative abuse potential, and its likelihood of causing dependence when abused.
Coverage Determination (CD)	Any decision (i.e., an approval or denial for a prescription drug) made by KHS or its Pharmacy Benefit Manager (PBM), regarding payment or benefits to which a Member believes he or she is entitled. A. Receipt of, or payment for, a prescription drug that a Member believes may be covered; B. A tiering or Formulary Exception request; C. The amount that the plan sponsor requires a Member to pay for a Part D prescription drug and the Member disagrees with the plan sponsor; D. A limit on the quantity (or dose) of a requested drug and the Member disagrees with the requirement or dosage limitation; E. A requirement that a Member try another drug before the plan sponsor will pay for the requested drug and the Member disagrees with the requirement; F. A decision whether a Member has, or has not, satisfied a Prior Authorization or other Utilization Management requirement. Presentation of a prescription at the pharmacy counter is not a CD.
Dismissal	A decision not to review a request for an initial determination because it is considered invalid or does not otherwise meet Medicare Part D requirements.

D-SNP/SNP	Dual Special Needs Plan or Special Needs Plan. Medicare Advantage coordinated care plans that serve the special needs of certain groups of individuals including institutionalized individuals (as defined by CMS), those entitled to Medical Assistance under a State Plan under Title XIX and individuals with severe or disabling chronic conditions, as defined by CMS.
Effectuation	Payment of a claim, authorization or provision of a benefit KHS has approved. For the purpose of this policy, effectuate is intended to include oral and written notification to the Member, written notification to the prescriber and override entry in PBM claims payment system so that a claim is paid.
Exceptions	Exceptions are types of CDs. Requests for coverage of a non-formulary Part D covered drug, changing the tier copay ("tiering exception") or waiver of Prior Authorization requirements.
Formulary	A list of Part D drugs covered by KHS for Members enrolled in its plans/ The Formulary is a continually updated list of medications and related information, representing the clinical judgment of physicians, pharmacists, and other experts in the diagnosis and/or treatment of disease and promotion of health.
Independent Review Entity (IRE)	An independent entity contracted by CMS to review adverse level 1 (redetermination) appeal decisions made by the plan.
Low Income Cost-share Subsidy (LICS)	Medicare subsidy specific to Part D for qualified beneficiaries in the form of reduced co-payments.
Member	A beneficiary enrolled in KHS.
Pharmacy Benefits Manager (PBM)	Perform Rx is KHS's PBM and provides the Point of Service (POS) claims processing system for pharmacy claims.
Part D Drug	A drug that may be dispensed only upon a prescription, is being used for medically-accepted indication as defined by section 1927(k)(6) of the Social Security Act, and is one of the following: A. A drug that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act; B. A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act; C. Insulin described in section 1927(k)(2)(C) of the Act; D. Medical supplies associated with the delivery of insulin; E. A vaccine licensed under section 351 of the Public Health

	Service Act and its administration.
Point of Service (POS)	At the pharmacy point of service.
Prior Authorization (PA)	An evaluation of the drug's prescribed use against a predetermined set of CMS approved criteria in order to determine whether the drug/drug class will be covered by the beneficiary's insurance plan.
Provider Supporting Statement	Reasons provided by the prescriber when a drug being requested is not on the Formulary or the prescriber requests a waiver of the UM requirements. The statement has to indicate reasons why the Member cannot use a Formulary drug, a Formulary drug with no Utilization Management (UM) edits or a lower-cost sharing drug. A statement of medical justification consistent with the requirements set forth in Title 42 of the Code of Federal Regulations, Section 423.578(b)(5).
Quantity Limits (QL)	Dose restriction, including the number and/or dosage form, that causes a particular Part D drug not to be covered for the number of doses and/or dosage form prescribed
Step Therapy (ST)	Particular Part D drug not to be covered until the requirements of the plan's coverage policy are met, which requirements are approved by CMS.
Redetermination	Level one (1) Part D appeal which reviews an adverse CD, including the findings upon which the decision was based and any other submitted evidence.
Reopening	A remedial action taken to change a binding determination or decision even though the determination or decision may have been correct at the time it was made.
Tolling	Delaying the start of and extending the timeframe of review for a standard or expedited Exception request if the plan is waiting to receive the prescriber's supporting statement. A plan may toll a request for up to fourteen (14) days. Reimbursement requests are not eligible for tolling.
Utilization Management (UM) Edits	Requirements for the approval of a drug which can be one of the following: prior authorization (PA), step therapy (ST), or a quantity limit (QL).
Withdrawal	A verbal or written request to rescind or cancel an initial determination.

IV. PROCEDURES

A. Request for Coverage Determination (CD) for Medicare Part B versus Medicare Part D Drugs

1. KHS shall not consider a drug prescribed to a Member for a Covered Part D Drug if payment for such drug is available (or would be available but for the application of a deductible) under Medicare Part A or Medicare Part B for that Member.

2. KHS and/or its PBM will rely on information submitted by the point of service (POS) pharmacy or Prescriber to communicate the diagnosis or the location where the medication is going to be administered to determine drug coverage under Medicare Part B versus Medicare Part D.
    a. The POS Pharmacy may be required to share the information provided on the prescription to assist in the determination of Part B vs. Part D coverage.

3. Part B vs. Part D CDs will be based on guidance set forth by the Centers for Medicare and Medicaid Services (CMS).

B. Medications to be Considered and Additional Parameters for Making Part B vs. Part D CDs

1. Durable Medical Equipment Supply Drugs – Infusion Drugs
    a. Any agent administered in the home via intravenous (IV) drip or push injection would be covered under Part D.
    b. If the drug is infused using an implantable pump, administered using a CMS-approved infusion pump, or meets durable medical equipment-maximum allowable cost (DME-MAC) Local Coverage Determination (LCD) criteria, it will be covered by Part B.
    c. The exception to this rule is if the Member resides in a long-term care (LTC) facility and the drug is administered via an infusion pump, then the medication is covered under Part D.

2. Durable Medical Equipment Supply Drugs – Respiratory Drugs
    a. Inhalation drugs administered in the home via a hand-held inhaler (ex. Metered Dose Inhaler or other non-nebulized administration) would be covered under Part D.
    b. If the drug's approved administration is through a nebulizer in the home, it will be covered by Part B.
    c. The exception to this rule is if the Member resides in an LTC facility and the drug is administered via a nebulizer, then the medication is covered under Part D.

3. Intravenous Immune Globulin (IVIG) provided in the home

a. For Members whose diagnosis is primary immune deficiency disease, IVIG is covered by Part B.

b. All other medically accepted indications are covered under Part D.

4. Parenteral Nutrition

    a. For Members with a non-functioning digestive tract, parenteral nutrition is covered by Part B.

    b. All other medically accepted indications are covered under Part D.

5. Oral Anti-neoplastic Drugs for which there is an infusible version of the drug

    a. If the drug is related to the Member's cancer treatment, it will be covered under Part B.
    b. All other medically accepted, non-oncology indications are covered under Part D.
    c. As determined by CMS, oral anti-cancer drugs that have no other medically accepted indication besides cancer treatment, should not be included on the KHS Formulary.

6. Oral Anti-emetic Drugs

    a. If the use is related to the Member's cancer treatment, a full replacement for intravenous administration within forty-eight (48) hours of cancer treatment, the medication will be covered under Part B.

        i. Aprepitant (Emend®) will be covered under Part B when it is given prior to, during or right after chemotherapy.

    b. Oral anti-emetic drugs dispensed for use after the forty-eight (48)-hour period, or any oral anti-emetic prescribed for conditions other than treatment of the effects of cancer treatment, will be covered under Part D.

7. Immunosuppressant Drugs

    a. Drugs used in immunosuppressive therapy for a Member who has received a Medicare covered organ transplant are covered under Part B.
    b. Immunosuppressant drugs used for other conditions, likely for auto-immune conditions, are covered under Part D.

8. Injectables

    a. Coverage for Part B vs. Part D cannot generally be determined based solely on the drug itself. How the drug was "prescribed and dispensed or administered" with respect to the individual must be considered. The same drug may be covered under different circumstances either by Part B or Part D.

b. KHS will cover Part D eligible injectable drugs not covered by Medicare Part B. Most of these are generally self-administered (e.g., Imitrex).

c. The fact that an injectable is covered under Part B if provided by and administered in a Physician's office or hospital outpatient setting does not mean KHS will deny a claim from a Pharmacy solely based on availability of Part B coverage for drugs given in the Physician's office. If, however, a Member submits an out-of-network claim for an injectable drug administered in-office from a Physician's supply, and this drug is covered in that setting by the Part B contractor for that area, such a claim will be denied under Part D by KHS based on Part B coverage requirements.

d. If the medication (including injectable) is being obtained at a retail pharmacy, it may be covered under Part D in accordance with the corresponding National Coverage Determination (NCD) or LCD.

9. Hemophilia Clotting Factors

    a. Hemophilia clotting factors for hemophilia patients, and items related to the administration of such factors, are always covered under Part B and never under Part D.

10. Pneumococcal Vaccine
    a. All vaccines must be dispensed and administered in compliance with California state law.
    b. The Pneumococcal vaccine and its administration to a Member are covered under Part B.

11. Hepatitis B Vaccine
    a. All vaccines must be dispensed and administered in compliance with California state law.
    b. The Hepatitis B vaccine and its administration to a Member who is at high or intermediate risk of contracting Hepatitis B are covered under Part B.
    c. The Hepatitis B vaccine prescribed to be administered prophylactically will be covered under Part D.

12. Influenza Vaccine

    a. All vaccines must be dispensed and administered in compliance with California state law.

    b. The Influenza vaccine and its administration to a Member are covered under Part B.

13. Antigens

    a. These formulations are usually prepared by a Physician (e.g., an allergist) for a specific patient. The Physician or Physician's nurse generally administers these drugs in the Physician's office.

b. Antigens would be covered under Part B.

14. Drugs for End-Stage Renal Disease (ESRD) Treatment

    a. All drugs and biologicals used for the treatment of ESRD are included in the ESRD Prospective Payment System (PPS) bundled payment and are not separately paid. The ESRD PPS is covered under Part B.

    b. Drugs for ESRD treatment include, but are not limited to the categories below:

        i. 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.

        ii. Anemia Management – drugs used to stimulate red blood cell production and/or treat or prevent anemia. This category includes erythropoietin Stimulating Agents (ESAs) and iron.

        iii. Bone and Mineral Metabolism – drugs used to prevent/treat bone disease secondary to dialysis. This category includes phosphate binders and calcimimetics.

        iv. Cellular Management – drugs used for deficiencies of naturally occurring substances needed for cellular management. This category includes levocarnitine.

    c. For ESRD patients not receiving dialysis, the drugs can be filled in the retail setting and covered under Part D.

15. Pre-exposure Prophylaxis (PrEP) for Human Immunodeficiency Virus (HIV) Prevention

    a. If an antiretroviral drug (whether oral or injectable) is being used for HIV PrEP, this will be covered under Part B.

    b. If it is being used for HIV treatment or HIV postexposure prophylaxis (PEP), this will be covered under Part D.

C. Denials

1. If the request is not consistent with Part D coverage, then the Part D CD will be denied as a "Non-Covered Benefit."

2. The Member or Member's Appointed Representative, and the Member's Prescribing Physician, or other Provider of health care services for the Member will receive a Notice of Denial of Medicare Prescription Drug Coverage.

a. The Notice of Denial of Medicare Prescription Drug Coverage shall provide an explanation that the medication is denied under Part D, but will include the conditions of approval under Part B.

3. For more information on the CD process and timeframe requirements, please see Policy 13.30-P, "Part D Coverage Determinations."

D. Delegated Oversight

1. KHS is responsible for ensuring that their delegates comply with all applicable state and federal laws and regulations, contract requirements, and other CMS guidelines and regulations. These requirements must be communicated by KHS to all delegated entities and subcontractors.

V. ATTACHMENTS

Attachment A:	N/A

VI. REFERENCES

Reference Type:	Specific Reference:
Regulatory	42 CFR §423.560, 42 CFR §413.215
Regulatory	Title 42 of the Code of Federal Regulations, Section 423.578(b)(5).
Regulatory	Part C&D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance - Section 50, 60, 70, 80, and 90 and Appendix 2 (11.18.2024)
Regulatory	Medicare Prescription Drug Benefit Manual, "Chapter 6 – Part D Drugs and Formulary Requirements" – Section 20 and Appendix C
Regulatory	Medicare Benefit Policy Manual, "Chapter 11 – End Stage Renal Disease (ESRD)"
Regulatory	Medicare Prescription Drug Benefit Manual, "Chapter 14 - Coordination of Benefits" – Section 50.15
Other KHS Policies	13.30-P Part D Coverage Determinations.

VII. REVISION HISTORY

Action	Date	Brief Description of Updates	Author
Effective	01/01/2026	New policy created to comply with D-SNP	M.C Pharmacy

VIII. APPROVALS

Committees | Board (if applicable)	**Date Reviewed**	**Date Approved**

Choose an item.		

Regulatory Agencies (if applicable)	**Date Reviewed**	**Date Approved**
Choose an item.		