KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Application of Medical Necessity and Application of Clinical Criteria	**Policy #**	30.64-P
Policy Owner	Utilization Management	**Original Effective Date**	01/01/2026
Revision Effective Date		**Approval Date**	01/16/2026
Line of Business	☐ Medi-Cal ☒ Medicare ☐ Corporate		

I. PURPOSE

To define the process by which Kern Health Systems (KHS) make Utilization Management (UM) determinations (e.g., approval, modifications, denials, or pended) based on medical necessity of proposed health care services, through the application of criteria or guidelines supported by sound clinical principles and processes, regularly reviewed, and updated and maintained to the most current version available.

II. POLICY

A. KHS use written clinical criteria based on sound clinical evidence in making utilization decisions in determining the medical necessity and appropriateness of health care services to include:

1. Providing a standardized written process for using and applying clinical criteria that is objective, based on the member's individual needs, and assesses the local delivery system.

B. This process is documented in KHS clinical systems as applicable for determinations regarding coverage of the service.

III. DEFINITIONS

Compliance Authority	As applicable in context, all federal, state, and local laws, and regulations; accreditation standards and requirements; the Policies and Procedures (P&Ps) are reviewed by the UM Committee and adopted to meet contractual requirements.
Clinical Criteria	Systematically developed and evidence-based clinical practice guidelines which assist practitioner and patient decisions about appropriate health care for specific circumstances.

Medical Necessity	Health care services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine.
Reasonable and Necessary	The definition has three main elements, in accordance with Centers for Medicare and Medicaid Services (CMS) Final Rule including that an item or service: A. Be safe and effective, B. Not experimental or investigational, and C. Appropriate for Medicare patients.
Medical necessity guidelines (MNGs)	Medical policies that are developed to publish what services are covered, and to provide a better understanding of the basis upon which coverage decisions are made.
Nationally Recognized Medical Standards	Clinical criteria, practice guidelines and related standards established by national quality and accreditation entities generally recognized in the United States health care industry, i.e., Milliman Care Guidelines (MCG).
Utilization Review	A set of formal techniques designed to monitor the use of or evaluate the medical necessity, appropriateness, efficacy or efficiency of health care services, procedures or settings, including prior authorization, second opinion, certification, concurrent review, case management, discharge planning or retrospective review, in order to make a determination regarding coverage of the service
Medicare Coverage Determination Process	Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury (and within the scope of a Medicare benefit category). National coverage determinations (NCDs) are made through an evidence-based process, with opportunities for public participation. In the absence of a national coverage policy, an item or service may be covered at the discretion of the Medicare contractors based on a local coverage determination (LCDs)
Medical or Scientific Evidence	Evidence found in any of the following sources: A. A peer-reviewed scientific study published in or accepted for publication by a medical journal that meets nationally recognized requirements for scientific manuscripts, and which journal submits most of its published articles for review by experts who are not part of the journal's editorial staff. B. Peer-reviewed medical literature, including literature relating to a therapy reviewed and approved by a qualified institutional review board, biomedical compendia and other medical literature that meet the criteria of the National Institutes of Health's Library of Medicine for indexing in Index Medicus (Medline) and Elsevier Science Limited for indexing in Excerpta Medica (EMBASE).

	C. A medical journal recognized by the Secretary of Health and Human Services under section 1861(t)(2) of the Social Security Act (49 Stat. 620, 42 U.S.C. § 395x(t)(2)). D. One of the following standard reference compendia: 1. The American Hospital Formulary Service-Drug Information. 2. DRUGDEX Information System. 3. The American Dental Association Accepted Dental Therapeutics. 4. The United States Pharmacopoeia-Drug Information. E. Findings, studies or research conducted by or under the auspices of a United States government agency or nationally recognized Federal research institute, including: 1. The United States Agency for Healthcare Research and Quality. 2. The National Institutes of Health. 3. The National Cancer Institute. 4. The National Academy of Sciences. 5. The United States Department of Health and Human Services. 6. The Food and Drug Administration. 7. Any national board recognized by the National Institute of Health for the purpose of evaluating the medical value of heath care services. 8. Other medical or scientific evidence that is comparable to the sources specified in one (1), two (2), three (3), four (4), and five (5) above.

IV. PROCEDURES

A. KHS utilize evidence-based clinical criteria from nationally recognized authorities to guide UM decisions involving pre-service, concurrent review, and post service decisions in conjunction with the member's individual needs and assessment of local delivery system

1. Guidelines set forth in Medicare regulations, manuals and instructions including evidence -based clinical criteria sources but not limited to:
    a. Eligibility
    b. Benefit document: Evidence of Coverage (EOC)
    c. Medicare Benefit Policy Manual.
    d. Medicare Claims Processing Manual; and
    e. Medicare Managed Care Manual.
    f. CMS Drug Compendia
    g. CMS National Coverage Determinations (NCD)
    h. Coverage decisions by local Medicare Administrative Contractors (MACs) with jurisdiction for claims in California. Noridian is the designated MAC for Part A,

Part B, Durable Medical Equipment (DME) claims and National Government Services (NGS) for home health and hospice claims.

i. Local Coverage Determinations (LCD)
j. Local Coverage Articles (Active & Retired) 005 Confidentiality and Disclosure of Information
k. Other MAC-based coverage bulletins
l. Health Plan Medical Policies
m. In the absence of Medicare guidelines Nationally recognized evidenced based guidelines (i.e., MCG, InterQual, Americans with Disabilities Act (ADA), Affordable Care Act (ACA)) will be utilized.
n. InterQual Criteria or MCG guidelines may be used in connection with the independent professional judgment of a qualified professional.

2. For Part B Drug and Biologicals Only:
    a. Medicare Approved Drug Compendia and/or relevant guidance from the Food and Drug Administration (FDA) according to the rules in the Medicare Benefit Policy Manual Chapter fifteen (15), Section 50.4 and sub-chapters, paying special attention to the distinctions for anticancer chemotherapy regimen drugs (50.4.5) and immunosuppressive drugs (50.5.1),
    b. And If Applicable
        i. Organization Specific Guidelines for Part B Drug Step Therapy or organization Specific Guidelines for Device Preferred Products. Step therapy guidelines can only be applied to drugs not used within the last Three hundred and sixty- five (365) days.

3. For Medi-Cal Line Benefits not covered by Medicare:
    a. In accordance with applicable federal and state guidelines, the following order of precedence shall be observed:
    b. Criteria required by applicable state or federal regulatory agency
    c. Medi-Cal Provider Manuals Part two (2)
    d. Title 22
    e. Evidence-based guidance addressing new or existing technology, such as Milliman Care Guideline (MCG), and Hayes.

4. Medicare Hierarchy of Clinical Criteria Application - Licensed reviewers must follow this sequence, documenting the source and rationale:
    a. Eligibility & Evidence of Coverage (EOC)
    b. Medicare Benefit Policy Manual
    c. Medicare Inpatient-Only List (if inpatient review)
    d. National Coverage Determinations (NCD)
    e. Local Coverage Determinations/Articles (LCD/LCA)
    f. MCG or InterQual
    g. Internally developed criteria

    Example: Case Note Requirement: “Source # [ ]: [Name] – [Rationale]”

5. When UM Criteria are applied, an assessment of the local delivery system's ability to meet a member's specific health care needs is required, and the following should be considered:
    a. Inpatient, Outpatient, and transitional care is available within the service area
    b. Availability of outpatient services in lieu of inpatient services such as surgery centers vs. inpatient surgery
    c. Availability of highly specialized services such as transplant facilities or cancer centers
    d. Availability of skilled nursing facilities, subacute care facilities or home care in the services area to support the member after hospital discharge
    e. Local hospitals' ability to provide all recommended services within the estimated length of stay.
    f. Other factors that may impact the implementation of an individual member's care plan.
    g. Benefit Coverage

6. Only a licensed physician or a licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, may deny or modify requests for authorization of health care services for members for reasons of medical necessity.

B. Application of Medical Necessity and Utilization Review Criteria, and the procedures for applying them, are annually approved, and updated when appropriate.

C. KHS evaluates, at least annually, the consistency with which all appropriate clinical and non-clinical staff included in utilization review applies appropriate criteria for decision-making. (Please refer to policy 30.71-P, D-SNP UM-Inter-Rater Reliability Audits).

D. KHS will disclose to network practitioners, members, member's representatives, or the public, upon request, the clinical guideline or criteria used to make utilization review determinations.
    1. Requests of criteria may be made in person, at KHS Place of Business or by telephone. The distribution of the clinical guidelines or criteria may be in writing by mail when practitioners do not have fax, email or internet access, fax, telephonic, via Provider Manual, Provider Bulletin, on its website, or e-mail and must be accompanied by the following notice:
        a. The material provided to you are guidelines used by this plan to authorize, modify, or deny care for person with similar illnesses of conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract.
        b. KHS maintains a record of the request(s) for disclosure and copies of responses to Providers, Members, and the Public. All disclosures will be maintained in the disclosure log and presented to the UM committee meeting on an annual basis.
            i. Disclosure includes policies, procedures, and criteria used to make a determination for requests submitted by contracted and non-contracted healthcare practitioners and providers.

E. KHS entities shall proactively publish all internal coverage criteria on a publicly accessible website, subject to the following:
    1. Criteria must be viewable without any user registration, login, subscription, or paywall.
    2. No restriction solely to plan members, contracted providers, or requestors.

3. Access must not require completion of surveys, extensive forms, or any other unnecessary data collection.

F. G. Utilization of Criteria exemptions:

1. Prior authorization guidelines do not apply to the following:
    a. Emergency and post-stabilization services for medical/behavioral health, urgent care, crisis stabilization, urgent care for home and community service-based recipients, family planning, preventive services, basic prenatal care, communicable disease services including Sexually Transmitted Disease (STD) and Human Immunodeficiency Virus (HIV), out of area renal dialysis and tobacco cessation services.

2. Prior authorization requirements are not applied to Emergency Services for network or out-of-network providers.

KHS is responsible for ensuring that their delegates comply with all applicable state and federal laws and regulations, contract requirements, and other CMS, Department of Healthcare Services (DHCS), and or Department of Managed Health Care (DMHC) guidance, including applicable All Plan Letters (APLs), Health Plan Management Systems (HPMS) memos, Policy Letters, and Dual Plan Letters. 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 Code of Federal Regulations (CFR) S 422.214
Regulatory	Health & safety Code (H&SC) Sections 1317.1, 1371.35 & 1371.
Other	National Committee for Quality Assurance (NCQA) Guidelines and Standards

VII. REVISION HISTORY

Action	Date	Brief Description of Updates	Author
Effective	01/01/2026	New Policy created to comply with D-SNP.	UM

VIII. APPROVALS

Committees | Board (if applicable)	**Date Reviewed**	**Date Approved**
Choose an item.		
Choose an item.		

Regulatory Agencies (if applicable)	**Date Reviewed**	**Date Approved**
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