



KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Requests for Experimental and Investigational Services	Policy #	30.87-P
Policy Owner	Utilization Management	Original Effective Date	01/01/2026
Revision Effective Date		Approval Date	12/15/2025
Line of Business	<input type="checkbox"/> Medi-Cal <input checked="" type="checkbox"/> Medicare <input type="checkbox"/> Corporate		

I. PURPOSE

To define the Kern Health System process of reviewing requests for experimental and investigational services in accordance with Centers for Medicare & Medicaid Services (CMS) and CA H&S Code Regulations.

II. POLICY

- A. Experimental and Investigational services and/or procedures are generally not covered, while services which demonstrate a significant body of scientific evidence supporting safety and effectiveness may be considered for coverage based on medical necessity. The experimental and investigational status of a particular medical service may be updated at any time, based on new/updated information.
- B. Kern Health Systems (KHS) identifies certain medical services to be Experimental and Investigational.
- C. These services include drugs, biologics, treatments, surgical and medical procedures, diagnostic tests, devices, technology, and supplies that do not have established scientific efficacy in the diagnosis and/or management of certain conditions.
- D. Experimental and Investigational services do not represent standards of medical care and, therefore, do not meet criteria for medically necessary services.
- E. KHS will not cover services identified as Experimental and Investigational.
- F. A KHS Medical Director/ Designated Physician Reviewer will consider coverage for possible exceptions when it is medically necessary and covered under the member's Medicare Advantage prescription drug

plan (MAPD) benefit plan.

- G. KHS recognizes that certain investigational medical devices not yet approved for marketing may be researched as part of a Food and Drug Administration (FDA) approved clinical trial.
- H. This policy establishes guidelines for review of devices with “Investigational Device Exemptions” and those approved by the FDA under “Humanitarian Device Exemptions.”
- I. Services that are considered Experimental and Investigational are not covered by the member’s individual benefit plan. In the event that the Centers for Medicare & Medicaid Services (CMS) has a Local Coverage Determination (LCD), National Coverage Determination (NCD), or other CMS coverage document in place regarding a procedure, service, or device deemed Experimental and Investigational KHS will utilize the relevant LCD, NCD, or other CMS coverage document on that procedure, service, or device for KHS Medicare (DSNP) Members.
 - 1. This includes interventions or devices for which CMS has established “coverage with evidence development, (CED)”.
 - 2. The specific criteria and coding laid out by CMS for these interventions must be met, and the members must be enrolled in a specific clinical trial listed.
- J. The state of California requires that every health care service plan provides an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual members who meet all the following criteria:
 - 1. The member has a life-threatening or seriously debilitating condition, as defined below.
 - 2. The member's physician certifies that the member has a life-threatening or seriously debilitating condition for which standard therapies have not been effective in improving the condition of the member, for which standard therapies would not be medically appropriate for the member, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed below:
 - a. For this policy is defined as a treatment, services, or supplies deemed experimental and/or investigational through a determination made by Health Plan.
 - 3. From Section 1370.4 of the California Health & Safety Code "Life-threatening means either or both of the following:
 - a. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted.
 - b. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.

4. Seriously debilitating means diseases or conditions that cause major irreversible morbidity.

III. DEFINITIONS

TERMS	DEFINITIONS
Experimental and Investigational Services	<p>Medical services identified by KHS that lack peer-reviewed published evidence of safety and efficacy, and/or are not recognized as standards of care in the diagnosis and management of certain conditions.</p> <p>A medical service will be considered Experimental and Investigational if any of the following criteria apply:</p> <ol style="list-style-type: none"> 1. There has not been final unrestricted market approval from the FDA or other appropriate government body, if applicable, for the specific use requested; or 2. Scientific evidence from peer-reviewed published literature: <ol style="list-style-type: none"> a. Is insufficient to evaluate if there is a health benefit; or b. Does not establish conclusive benefit in health outcomes; or c. Does not demonstrate equal or greater benefit than accepted standard treatment alternatives or medical services; or d. Does not conclusively establish the health outcomes benefit from using the medical service; or e. Health outcome benefit is not demonstrated to be obtainable (reproducible) in non-investigational settings.
Coverage with Evidence Development (CED)	<p>When the available evidence on a device or service is insufficient to support coverage outside the context of a well-designed clinical research study, Centers for Medicare & Medicaid Services (CMS) may make a national coverage determination (NCD) that requires participation in certain clinical trials, longitudinal studies, or registries for coverage. NCDs requiring CED are listed on the CMS website and contain information on the specific requirements for CED along with approved clinical studies. These NCDs also serve as non-coverage documents outside of CED. For CED, clinical research studies and registries must meet a set of specific CMS study criteria and be formally approved by CMS; such studies are registered on the www.ClinicalTrials.gov website by the trial Sponsor /Principal Investigator.</p>
FDA Device Classifications	<p>All medical devices must be manufactured under a quality assurance program, be suitable for the intended use, be adequately packaged and properly labeled, and have registration and device listing forms on file</p>

with the FDA.

1. Class I Device – Devices are subject to a comprehensive set of regulatory authorities called general controls that are applicable to all classes of devices.

- a. **General Controls** – Apply to all classes of medical devices and provide the FDA with the means of regulating devices to assure their safety and effectiveness. These include (but are not limited to) provisions that relate to registration and device listing; premarket notification (most class I devices are exempt by regulation from premarket notification requirement); prohibitions against adulteration and misbranding; records and reports; and good manufacturing practices.

2. Class II Device – Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.

- a. **Special Controls** – Can include the promulgation of performance standards as well as post-market surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions), and other appropriate actions as the FDA deems necessary to provide such assurance.

3. Class III Device – Devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require premarket approval.

- a. **Premarket Approval (PMA)** – The required process of scientific review to ensure the safety and effectiveness of Class III devices. Not all Class III devices require a Premarket Approval application to be marketed. Class III devices which require premarket approval are those:
 - i. Regulated as new devices prior to May 28, 1976, (e.g., transitional devices);
 - ii. Devices found to not be substantially equivalent to devices marketed prior to May 28, 1976;
 - iii. Class III pre-amendment devices which, by regulation in 21 CFR, require a premarket approval

	<p>application.</p> <p>iv. 510(k) – A premarket notification made to the FDA to demonstrate that the device, to be marketed, is substantially equivalent to a device legally marketed before May 28, 1976 (predicate device), for which a PMA is not required.</p>
Humanitarian Use Device (HUD)	A device that the FDA has determined is intended to benefit patients in the treatment and/or diagnosis of diseases or conditions that affect or are manifested in fewer than four thousand (4000) individuals in the US per year. The use of an HUD within its approved labeling does not constitute research; however, the FDA requires Institutional Review Board (IRB) review and approval before an HUD is used.
Humanitarian Device Exemption (HDE)	An application submitted to the FDA that is similar in form and content to a PMA but is exempt from the effectiveness requirements of a PMA. HDE restricts HUDs from being sold for profit, except in narrow circumstances, and allows them only to be used following IRB approval for use in a specific facility, except in certain emergencies. While results from clinical investigations are not required, the HDE application must contain sufficient information to indicate that the device does not pose an unreasonable or significant risk of illness or injury, the probable benefit outweighs the risk from its use, and to demonstrate that no comparable devices are available to treat or diagnose the disease/condition.
Investigational Device Exemption (IDE)	<p>Typically required to support a PMA or 510(k), an exemption approved by the FDA (if a significant risk device) that allows an investigational device to be used in a clinical study approved by an Institutional Review Board (IRB) to collect safety and effectiveness data, and/or to evaluate modifications or newly intended uses of legally marketed devices. All such clinical evaluations of investigational devices, unless exempt, must have an approved IDE before the study is initiated. The FDA assigns all approved IDEs to one of two categories:</p> <ol style="list-style-type: none"> 1. Category A (Experimental) a device for which the ‘absolute risk’ of the device type has not been established (initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether these device types can be safe and effective. 2. Category B (Nonexperimental/investigational) a device for which the incremental risk is the primary risk in question (initial questions of safety and effectiveness of that device type have

	been resolved), or it is known that the device type can be safe and effective, because other manufacturers have obtained FDA PMA or clearance for that device type.
Medical Device	An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, which, established by the U.S. Federal Food Drug & Cosmetic Act, Section 201 (h), is: <ol style="list-style-type: none"> 1. Recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them 2. Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals 3. Intended to affect the structure or any function of the body of humans or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
Medical Services	Drugs, biologics, treatments, surgical and medical procedures, diagnostics, devices, technology, and supplies/equipment used for the prevention, diagnosis, and/or treatment of healthcare conditions.
Life Threatening	Defined in CA H&S Code to means either or both of the following: <ol style="list-style-type: none"> 1. Diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted. 2. Diseases or conditions with potentially fatal outcomes, where the end point of clinical intervention is survival.
Seriously debilitating	Defied in CA H&S Code to mean diseases or conditions that cause major irreversible morbidity.
Institutional Review Board (IRB)	The IRB evaluates study design to minimize risks and ensures participants are treated ethically.

IV. PROCEDURAL REQUIREMENTS

A. Specific Indications

A medical service (see Definition), or expanded application of an existing medical service, will be considered Experimental and Investigational if any of the following criteria is met:

1. The medical service is being delivered or should be delivered subject to the approval and supervision of an IRB, as required and defined by federal regulations or other official actions (especially those of the FDA and the Department of Health and Human Services (DHHS))
 2. Peer-reviewed published literature does not support the clinical validity, utility, and/or safety and efficacy of the medical service; or
 3. The predominant opinion among experts, as expressed in peer-reviewed published literature, is that the usage/provision of the medical service should be confined to investigational settings;
 4. The medical service has not been approved by appropriate regulatory agencies (e.g., FDA) for the specific intended use or purpose;
 5. The medical service is not considered to be Experimental or Investigational based on the above criteria, but it would not be medically necessary except for its use in conjunction with a medical service that is Experimental and Investigational (e.g., lab tests or imaging ordered to evaluate the safety and/or effectiveness of an Experimental and Investigational therapy);
 6. The medical service cannot lawfully be marketed without the approval of the FDA, and such approval has not been granted at the time of the use/provision or proposed use/provision of the medical service.
 7. The medical service is the subject of a current investigation of a new drug or new device application on file with the FDA.
 8. The medical service is the subject of an ongoing clinical trial (Phase I, II or the research arm of Phase III), as defined in regulations and other official publications issued by the FDA and/or DHHS.
- B. The state of California requires that every health care service plan provides an external, independent review process to examine the plan's coverage decisions regarding experimental or investigational therapies for individual members who meet all the following criteria:
1. The member has a life-threatening or seriously debilitating condition, as defined above.
 2. The member's physician certifies that the member has a life-threatening or seriously debilitating condition for which standard therapies have not been effective in improving the condition of the member, for which standard therapies would not be medically appropriate for the member, or for which there is no more beneficial standard therapy covered by the plan than the therapy proposed below.
- C. KHS's decision to delay, deny, or modify experimental or investigational therapies is subject to the independent medical review process.
- D. The independent medical review process must also meet the following criteria:

1. The plan will notify eligible enrollees in writing of the opportunity to request an external independent review after the decision to deny coverage.
2. If the enrollee's physician determines that the proposed therapy would be significantly less effective if not promptly initiated, the analyses and recommendations of the experts on the panel will be rendered within seven days of the request for expedited review.
3. Each expert's analysis and recommendation shall be in written form and state the reasons the requested therapy is or is not likely to be more beneficial for the enrollee than any available standard therapy, and the reasons that the expert recommends that the therapy should or should not be provided by the plan, citing the enrollee's specific medical condition, the relevant documents provided, and the relevant medical and scientific evidence, including, but not limited to, the medical and scientific evidence as defined below, to support the expert's recommendation.
 - a. Coverage for the services required under this section shall be provided subject to the terms and conditions generally applicable to other benefits under the KHS CMS-DHCS contract.

E. Upon request through Program Exception from the member's treating provider, Kern Health System Utilization Management (KHSUM) medical directors will consider circumstances identified by the provider in which treatment may provide significant benefit for the member and/or be a more cost-effective intervention.

F. The UM staff assigned to perform the review obtains clinical information according to KHS P&Ps for Prior authorizations.

G. The UM Physician Reviewer Medical Director determines if the requested service is medically necessary and appropriate according to policy.

H. If the review decision is denied by KHS, the member and requesting provider will be notified in writing of the right for the review to go under an Independent Medical Review as itemized in Section D. above.

KHS is responsible for ensuring that their delegates comply with all applicable state and federal laws and regulations, contract requirements, and other CMS, DHCS, and or 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
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VI. REFERENCES

Reference Type:	Specific Reference:
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Regulatory	Title 42 , Chapter IV , Subchapter B ,Part 405 Subpart B Medical Services Coverage Decisions That Relate to Health Care Technology
Other KHS Policies	30.64-P Application of Medical Necessity and Clinical Criteria, 30.92-P Prior Authorization Referrals, and 30.65-P Referral Processing Turn Around Times
Regulatory	CA Health and Safety Code (HSC) Section 1370.4, Experimental or Investigational Therapies
Regulatory	42 CFR 422.101 Requirements for Coverage Medicare Benefits Policy Manual Pub. 100-02 Chapter 14: Medical Devices:
Regulatory	Medicare Benefits Policy Manual Pub. 100-02 Chapter 16 Parts 10, 20, and 40: Medicare Benefit Policy Manual Medicare Clinical Trial Policy:
Regulatory	CMS 42 Chapter IV Subpart B Part 422 Subpart M Subpart M—Grievances, Organization Determinations and Appeals:
Regulatory	42 CFR§ 422.568 42 CFR § 422.562 General provisions. and 42 CFR § 422.572 Organization Determinations and Appeals
Regulatory	Title 22, CCR 51303-Excluded Services: § 51303
Regulatory	U.S. Federal Food Drug & Cosmetic Act, Section 201 (h)

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
Choose an item.		
Choose an item.		
Choose an item.		

