KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES			
Policy Title	Drug Utilization and Non-Formulary Treatment Request	**Policy #**	13.01-P
Policy Owner	Pharmacy	**Original Effective Date**	08/1997
Revision Effective Date	9/16/2024	**Approval Date**	12/11/2024
Line of Business	☒ Medi-Cal ☐ Medicare		

I. PURPOSE

The policy provides directions and parameters on how pharmacy authorization requests are processed. Pertinent regulatory elements are identified. These are used when reviewing requests for a decision.

II. POLICY

The following applies to pharmacy authorization requests that will be billed on a pharmacy NCPDP claim prior to the launch of Medi-Cal Rx and those medical supplies and devices remaining with the managed care plans outlined by the Medi- Cal Rx Scope document. All NCPDP pharmacy requests for claims for date of service after the launch of Medi-Cal Rx will be directed to Medi-Cal Rx for review. Until that time, these policies and protocols effectuated by Kern Health Systems will remain unchanged and in place. Institutional and professional claims will continue to be processed by the managed care plan and therefore the requests would follow these procedures outlined. Those drugs, medical supplies and devices will be reviewed as stated in this policy and the encounters submitted on an 837P file.

All non-formulary medications or formulas require prior authorization. Physician Administered Drugs (PADs) will be managed by a No Prior Authorization List. All PAD and similar not listed require prior authorization. All medically necessary outpatient prescription drugs, except for those specifically excluded from the Medi-Cal contract, shall be available to Kern Health System (KHS) Medi-Cal members.[1] This determination will be made through the non-formulary treatment request process as outlined in this policy and procedure.

The non-formulary treatment request process will conform to the requirements outlined in the following statutory, regulatory, and contractual sources:

A. Code of Federal Regulations Title 42 §§431.211; 431.213; and 431.214
B. California Health and Safety Code §§ 1367.01[2]; 1367.21; 1367.22; 1367.24
C. California Welfare and Institutions Code §14185
D. California Code of Regulations (CCR) Title 28 §1300.67.24

E. CCR Title 22 §§ 51003; 51014.1; 51014.2; 53854; 53894
F. DHS Contract Exhibit A - Attachment 5 (3)(F); Exhibit A –Attachment 10 (7)(F)
G. DHS MMCD Letters 04006 (November 1, 2004) and 05005 (April 11, 2005), and 08-013 (December 16, 2008).

This document shall be disclosed to the public upon request.[3]

III. DEFINITIONS

TERMS	DEFINITIONS
Chronic and Seriously Debilitating[4]	Diseases or conditions that require ongoing treatment to maintain remission or prevent deterioration and cause significant long-term morbidity.
Life Threatening[5]	Diseases or conditions (1) where the likelihood of death is high unless the course of the disease is interrupted and/or (2) with potentially fatal outcomes where the endpoint of clinical intervention is survival.

IV. PROCEDURES

A. SUBMISSION OF A NON-FORMULARY DRUG REQUEST

Non-Formulary drug requests can be made by KHS providers electronically via the secure KHS portal or on a 61-211 Form if one does not have access to the KHS Provider Portal. Portal submission is the preferred method. (See Attachment A). Form should be mailed/faxed to the following location:

KHS Pharmacy Department
2900 Buck Owens Boulevard
Bakersfield, CA 93308
661-664-5191

Staffing availability and working hours are Monday through Friday 8:00 am to 5:00 pm except holiday for inbound collect, or toll-free calls regarding review requests. After business hours 24-hour Telephone Triage Line (661)-632-1590 (Bakersfield) or 1-800-391-2000 (outside Bakersfield) (TTY 711).

Staff representative will state his/her name, title, and calling from Kern Family Health Care/ Kern Health Systems when initiating or returning calls.

KHS only requests information reasonably necessary to make a decision regarding the request.[6] Documentation must be complete and include:

1. Patient name.
2. CIN number.
3. Diagnosis with brief history.
4. Reason for request/justification including formulary medication failures.
5. Drug name, strength, directions, and National Drug Code.

6. Prescriber's name.

B. REVIEW OF TREATMENT AUTHORIZATION REQUEST (TAR)

Incoming requests are date and time stamped. Requests not submitted via the Provider Portal are formatted and data entered by staff. The initial gathering of information and preliminary decision is worked up by pharmacy technicians and forwarded to pharmacists or medical directors for review. All medical necessity determinations are made by the pharmacist or medical director. The Notice of Action (NOA) Letter is created, as necessary. If needing to be translated, the NOA Letter is sent to the Cultural & Linguistics Team. TAR review includes the actions outlined in the following table.

Action	Timeline	Comments
Review by Pharmacist or Medical Doctor (MD)		Evaluation for medical necessity denials signed by licensed pharmacist or MD[7]
Decision (approve or deny)	Within 24 hours of receipt.[8]	

Medications and supplies are evaluated based on appropriateness, efficacy, safety, pharmacokinetics, and cost effectiveness. Authorization may be granted only for Medi-Cal benefits that are medically necessary and do not exceed health care services received by the public generally for similar medical conditions. Authorizations may be granted only for the lowest cost item or service covered by the Medi-Cal program that meets the member's medical need.[9]

C. PRACTITIONER/PROVIDER AND MEMBER NOTIFICATION

Results of the TAR review are communicated by Pharmacy staff to the practitioner/provider and member as outlined in the following table. Notification to providers is provided via portal or facsimile if possible. The notification confirmation is attached to the request. If notice by electronic portal or facsimile is not possible, verbal notice is provided via phone within 24 hours of receipt. In such cases, written notice follows as outlined in the table below.

Result of Review	Practitioner/Provider Notice	Member Notice
Approved	Approved form[10] (within 24 hours of receipt).[11]	
Denied	Denied form (within 24 hours of receipt).[12]	Notice of Action Documents (within two (2) business days of the decision).[13] Documents include all of the following: A. Notice of Action – Denial (Attachments B) Your Rights Under Medi-Cal Managed Care & Form to File a State Hearing. Medi-Cal members only.

Notice of Action letters together with the indicated enclosures contain all the required elements for both provider and member notice of delay, denial, or modification including the following.[14]

1. The action taken.
2. A clear and concise explanation of the reason for the decision (including clinical reasons for decisions regarding medical necessity).
3. A description of the criteria/guidelines used. Providers may request a copy of the criteria used. Requests may be made by mail, fax, email, in person at the KHS administrative offices, or telephone. KHS will mail the criteria to those providers who do not have fax, email, or internet access. The criteria used are:
    a. Food and Drug Administration (FDA) approved indications.
    b. Medi-Cal coverage considerations
    c. National professional guidelines are used when applicable. (GINA, AACE, AHA, Etc.)
    d. Tertiary professional reviews are used as needed. (MCG, UpToDate, etc.)
    e. CMS excluded drug categories are applied when applicable to Medicaid plans.
4. A citation of the specific regulations or plan authorization procedures supporting the action.[15]
5. Information on how to file a grievance or an appeal for a denied/modified service with KHS including the Plan's name address and phone number.
6. Information regarding a Medi-Cal member's right to a State Fair Hearing including:
    a. The method by which a hearing may be obtained.
    b. That the member may either be self- represented or represented by an authorized third party such as legal counsel, relative, friend, or any other person.
    c. The time limit for requesting a fair hearing.
    d. The toll-free number for obtaining information on legal service organizations for representation.
7. Nondiscrimination Notice.
8. Language Assistance Taglines.
9. Information regarding the member's right to an Independent Medical Review with Department of Managed Health Care (DMHC).
10. DMHC required language regarding grievances.[16]
11. Name and telephone number of the pharmacy department.

D. DOCUMENTATION

Letters regarding authorization requests, including those sent by KHS to both members and providers, are retained as outlined in KHS Policy and Procedure #14.53-I – Records Retention.[17]

E. ALLOWED SUPPLIES OF MEDICATION

Members may receive up to a 30-day supply of medication. Women may receive up to 365-day supply of hormonal contraceptives.

1. Emergency Supplies[18]
   During weekends, holidays and non-business hours a pharmacy may choose to dispense enough medication (72 hours supply maximum) as an emergency supply to the member until the next working day, at the dispensing pharmacist's discretion according to pharmacy policy and procedures as defined by Title 22 section 51056.[19] If the medication is not on the Plan Formulary, a request must be submitted for payment processing stating the emergency and relevant clinical information about the member's condition and why they

were considered immediately necessary, and medication dispensed. A mere statement that an emergency existed is not sufficient. It must be comprehensive enough to support a finding that an emergency existed.[19] TAR approval is not needed for reimbursement before dispensing of 72-hour emergency supply of non-formulary drugs.

2. Exclusions
    a. Experimental services are not covered. Investigational services are not covered except when it is clearly documented that all of the following apply:
        i. Conventional therapy will not adequately treat the intended member's condition.
        ii. Conventional therapy will not prevent progressive disability or premature death.
        iii. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service.
        iv. The investigational service is the lowest cost item or service that meets the member's medical needs and is less costly than all conventional alternatives.
        v. The service is not being performed as a part of a research study protocol.
        vi. There is a reasonable expectation that the investigational service will significantly prolong the intended member's life or will maintain or restore a range of physical and social function suited to activities of daily living.[20]

    b. Services and supplies not primarily medical in purpose or which are common household items are not covered.[20]

    c. The following drugs or categories are limited for coverage [21]:
        i. The prescribed use is not for a medically accepted indication.
        ii. Agents when used for anorexia, weight loss, or weight gain.
        iii. Agents when used to promote fertility.
        iv. Agents when used for cosmetic purposes or hair growth.
        v. Agents when used for symptomatic relief of cough and colds*.
        vi. Vitamin and mineral products, except prenatal and fluoride preparations.
        vii. Nonprescription drugs*.
        viii. Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
        ix. Agents when used for the treatment of sexual or erectile dysfunction.
        x. Replacement of stolen or lost controlled drugs.

        *Exceptions to this rule are specifically listed in formulary, Member Handbook, or Prior Authorization List.

    d. The following are covered services but billed to the State Medicaid program:
        i. Psychotherapeutic agents.
        ii. Alcohol, heroin detoxification, and drug dependency treatment drugs.
        iii. Antiviral drugs to treat Human Immunodeficiency Virus/Acquired Immune

Deficiency Syndrome (HIV/AIDS).

iv. Blood factor products.

Please refer to the Medi-Cal manual under the Two-Plan Model.[22]

F. RETROSPECTIVE AUTHORIZATION REQUEST:

Retrospective authorization request may be submitted within sixty (60) calendar days from the date of service for services that are deemed urgent or emergent. All supporting documentation must be included with the request. Any request that requires prior authorization received by KHS with a date of service greater than sixty (60) calendar days will be denied.

All retrospective reviews will be completed within thirty (30) calendar days. KHS will communicate its decision to the provider within thirty (30) days of the receipt of determination, in a manner that is consistent with current law.

Failure to obtain prior authorization by the provider due to eligibility verification is not considered urgent or emergent.

1. Claim Denials for Services Performed without Obtaining Prior Authorization:
   Claims submitted by KHS contract and non-contract providers are matched against authorizations entered into the PBM claims payment system. Providers are required to determine a member's eligibility and obtain prior authorization before initiating non-emergent services. If the provider fails to obtain prior authorization or retrospective authorization as defined in section E for non-emergent services, the claim(s) for those services will be denied.

   Requests for retrospective payment for unauthorized services may be reviewed at the discretion of the health plan, and the decision to review will be based on the documentation submitted detailing the extenuating circumstances that explains why the prior authorization request was not submitted. All such requests must include complete medical records. Requests for retrospective authorization submitted only with records, will not be reviewed for medical necessity; but, instead denied as prior authorization was not obtained.

Providers may submit a Claims Dispute in accordance with KHS Policy 6.04-P.

G. CONTINUITY OF CARE[23]

Medi-Cal members are allowed continued coverage of a non-formulary single source drug which is part of a prescribed therapy previously approved for coverage by the plan for a medical condition of the member and the provider continues to prescribe the drug for the medical condition provided that drug is appropriately prescribed and is considered safe and effective for treating the member's medical condition. Nothing in this section shall preclude the prescribing provider from prescribing another drug covered by the plan that is medically appropriate.[23] If previously approved by a plan immediately prior to the date of enrollment, coverage may be continued until the prescribed therapy is no longer prescribed by a contracting practitioner.[24] Approval is contingent upon documentation that the patient had authorization from the previous plan of the medication at the time of enrollment no more than fifteen (15) days beyond the estimated day supply for the last documented pharmacy fill date.[23]

KHS does not require a new member to repeat step therapy when the member is already being treated for a medical condition by a prescription drug provided that the drug is appropriately prescribed and is considered safe and effective for the enrollee's condition. For purposes of this section, "step therapy" means a type of protocol that specifies the sequence in which different prescription drugs for a given medical condition and medically appropriate for a particular patient are to be prescribed.

Medi-Cal members are allowed continued coverage of a drug which is removed from the KHS formulary if the drug is part of a prescribed therapy in effect immediately prior to the date of removal until the prescribed therapy is no longer prescribed by a contracting practitioner.

H. BRAND NAME MEDICATIONS WHEN EQUIVALENT GENERIC BRAND IS AVAILABLE

If a medication is available or becomes available in an AB rated generic brand, the brand name version will become non-Formulary for KHS.

Unless it is determined to be medically necessary for the patient to continue using the brand name, if a generic brand becomes available during a patient's treatment, the patient will be expected to switch to the generic brand and must fail the generic brand prior to KHS granting authorization for the brand name.

Providers with patients having untoward effects from a generic brand must submit a completed FDA MedWatch form to KHS as part of the request for authorization to allow a brand name version instead of a generic brand. (See Attachment F).

Biosimilars and drugs considered as Follow Ons will be treated in the same fashion as if they were a traditional generic of the innovator drug. Per FDA rules, they are not automatically substitutable, but from clinical perspectives they are viewed as a generic version.

I. OFF-LABEL USE FOR LIFE THREATENING OR CHRONIC AND SERIOUS CONDITIONS[25]

1. Medi-Cal Product
   Section does not apply to the Medi-Cal product.[26]

2. Peer Reviewed Professional Society Endorsed Supporting Documentation
   If a physician or other provider wishes to prescribe a non-formulary or restricted FDA approved medication for an off-label use for a life threatening or chronic and debilitating condition, he/she may submit a referral or TAR to the Plan for the same. In the referral, the provider must demonstrate the medication is recognized for the treatment of that condition in one of the following sources:
   a. American Hospital Formulary Service's Drug Information.
   b. One of the following compendia, if recognized by the federal
   c. Centers for Medicare and Medicaid Services as part of an anticancer
   d. Chemotherapeutic regimen:
      i. The Elsevier Gold Standard's Clinical Pharmacology.

ii. The National Comprehensive Cancer Network Drug and Biologics Compendium.
iii. The Thomson Micromedex DrugDex.

e. Two articles from major peer reviewed medical journals that present data supporting the proposed off-label use or uses as generally safe and effective unless there is clear and convincing contradictory evidence presented in a major peer reviewed medical journal.

The provider is responsible for submitting the required documentation to KHS.[27]

J. SAMPLE MEDICATIONS[28]

Providers are discouraged from providing samples; however, if samples are given to the member, the entire course of therapy must be covered by the samples. Medications provided as samples do not establish a continuity precedent or satisfy step therapy criteria and, therefore, do not obligate coverage by KHS. If providing samples, Providers shall follow the outlined steps in KHS Policy and Procedure #13.23-P Pharmaceutical Standards.

K. TRIAL PERIOD[29]

Barring any medically adverse responses from the member, the trial period of a medication shall be determined per the recommended dosing titration guidelines presented to the FDA.

L. MONITORING[30]

The Compliance Department will conduct bi-annual audits to monitor compliance of the contracted emergency departments to provide a sufficient quantity of drugs to Medi-Cal members under emergency circumstances to last until the member can reasonably to be expected to have a prescription filled prior to leaving the emergency department. Issues discovered by this monitoring will be brought to the attention of the contracted emergency department and a Corrective Action Plan (CAP) will be required.

V. ATTACHMENTS

Attachment A: Treatment Authorization Request (TAR) Form (61-211)
Attachment B: Notice of Action – Denial letter
Attachment C: Notice of Action – Your Rights
Attachment D: Notice of Action – Nondiscrimination
Attachment E: Language Assistance Taglines
Attachment F: MedWatch form

VI. REFERENCES

Reference Type	Specific Reference
Regulatory	[1] Health and Safety Code (HSC) 1367.24. CCR Title 22 §53854(d),

	CCR Title 28 1300.67.24
Regulatory	[2] Applicable to pharmacy per Title 28 §1300.67.24(a)(1)
Regulatory	[3] HSC §1367.01(b)
Regulatory	[4] HSC §1367.21(e)
Regulatory	[5] HSC §1367.21(d)
Regulatory	[6] HSC §1367.01(g)
Other	[7] MMCD Policy Letter 08-013
Regulatory	[8] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to one (1) business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. DHS Contract A-5 3(F). Change to comply with CMS Managed Care final Rule Prior Authorization Process (§438.3(s)(6))
Regulatory	[9] CCR Title 22 § 51003
Regulatory	[10] Must include specific service approved (HSC §1367.01(h)(4))
Regulatory	[11] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to one (1) business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. HSC §1367.01(h)(3) requires notice to provider within 24 hours of the decision.
Regulatory	[12] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to one (1) business day. Although action must be taken on pain medications for the terminally ill within 72 hours, the Plan must follow the stricter Federal Medicaid 24 hours standard. HSC Section 1367.215. HSC §1367.01(h)(3) requires notice to provider within 24 hours of the decision. Change to comply with CMS Managed Care final Rule Prior Authorization Process (§438.3(s)(6))
Regulatory	[13] HSC §1367.01(h)(3) has the shortest time period for member notice (2 b/days of decision). CCR Title 22 Section 53894(a) and (d)
Regulatory	[14] HSC §1367.01(h)(4) and (5) and 1367.24(b); CCR Title 22 §53894
Regulatory	[15] Required for member notice only. CCR Title 22 §53894(d)(3)
Regulatory	[16] Required for member notice only. HSC §1367.24(b)
DHCS Contract (Specify Section)	[17] DHS Contract 03-76165 Exhibit A – Attachment 5 (2)(G)
Regulatory	[18] CCR Title 22 §53854(2)

Regulatory	[19] Title 22 51056
Regulatory	[20] CCR Title 22 § 51303
Regulatory	[21] Sec. 1927. [42 U.S.C 1396r-8]
Other	[22] Part 1 Medi-Cal Program Manual MCP: Two-Plan Model
Regulatory	[23] HSC 1367.22
Regulatory	[24] W&I Code 14185(c)
Regulatory	[25] Health and Safety Code §1367.21
Regulatory	[26] Plan shall reserve the right to modify this.
Regulatory	[27] HSC 1367.21 (b)
Other	[28] Section added upon request of the Director of Pharmacy (3/2/05). Language also included in Policy 2.24 – Pharmaceutical Guidelines
Other	[29] Section added upon request of the Director of Pharmacy (3/2/05).
Regulatory	[30] DHS/DMHC Medical Review Audit (YE 10/31/06).

VII. REVISION HISTORY

Action	Date	Brief Description of Updates	Author
Revised	2024-09	Per annual routine review, a purpose statement was added.	C.K. Pharmacy
Revised	2023-07	NCQA requirement for Language Assistance, staff working hours/availability, and TTY. Expanded process in Section 2, Review per NCQA recommendation. Section 3. C expanded per NCQA recommendation. Per NCQA added language and enhanced sections to accommodate PAD and other drugs billed via medical claims. APL 22-012 provides overall guidance on transition. DHCS File and Use 11/14/2023.	Pharmacy
Revised	2022-04	Policy attachments updated per APL 21-011 and APL 21-004. DMHC approval received on 6/10/2022. DHCS approval received on 7/19/2022.	Pharmacy
Revised	2021-07	Policy revised by Director of Pharmacy regarding changes in pharmacy authorizations and billing.	Pharmacy
Revised	2017-07	Policy revised to comply with CMS Final Rule on prior authorization process.	Pharmacy

		Attachments updated	
Revised	2017-03	Policy reviewed and updated by Director of Pharmacy. New Section 8.2 provides guidelines for prescribing medication for an off-label use for a life threatening or chronic and debilitating condition.	Pharmacy
Revised	2014-10	Formatting changes to policy, no material changes. Notice of Action letters (NOAs) revised as a result of the DHCS 2013 Medical Audit ending in 2014- CAF-9. "Your Right's Forms" updated to ensure continued compliance. Translation changes made to comply with MMCD APL 05005.	Pharmacy
Revised	2014-04	Language included in Section 1.0 to add time statement on authorization request. Revised to remove references to Health Families product.	Pharmacy
Revised	2013-07	Reviewed by Director of Pharmacy. Routine revision, updated Section 1.0 regarding submission of treatment authorization request.	Pharmacy
Revised	2009-10	Revision requested by Director of Pharmacy.	Pharmacy
Revised	2009-02	Revised to comply with MMCD Policy Letter 08-013. Notice of Action letters updated with language assistance services notice.	Pharmacy
Revised	2007-05	Revised per DHS/DMHC Medical Audit comment 5/13/2007.	Pharmacy
Revised	2007-04	Created Notice of Action Letters for Healthy Families product line per DHS/DMHC Medical Review Audit (YE 10/31/06).	Pharmacy
Revised	2005-07	Reviewed against MMCD Letters 04006 and 05005. New NOAs.	Pharmacy
Revised	2005-04	Continuity of care processes reviewed and revised. Reviewed against DHS Contract 03-76165 (Effective May 1, 2004).	Pharmacy
Revised	2004-05	Revised per DMHC/DHS Medical Audit YE Oct 03, finding 1.2. (Addition of member notice of modifications). New single letter for deferral, modification, or denial.	Pharmacy
Revised	2002-03	Revised per DHS comment 01/30/02.	Pharmacy
Revised	2002-01	DHS CAP Verification Visit Report (Med Rev YE 08/00).	Pharmacy
Revised	2001-02	changes made for 2000 Legislation submission – DMHC and DHS/DMHC Medical Review Audit (YE 08/31/00).	Pharmacy

VIII. APPROVALS

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

Regulatory Agencies (if applicable)	**Date Reviewed**	**Date Approved**
Department of Health Care Services (DHCS)	For APL 22-012	11/14/2023
Department of Health Care Services (DHCS)	For APL 21-011	07/19/2022
Department of Health Care Services (DHCS)	For APL 21-004	07/19/2022
Department of Managed Health Care (DMHC)	For APL 21-011	06/10/2022
Department of Managed Health Care (DMHC)	For APL 21-004	06/10/2022
Department of Health Care Services (DHCS)	DHS/DMHC Medical Review Audit	05/13/2007
Department of Health Care Services (DHCS)	DHS/DMHC Medical Review Audit	YE 10/31/06
Department of Health Care Services (DHCS)	DHS CAP Verification Visit Report	Med Rev YE 08/00
Department of Health Care Services (DHCS)	DMHC and DHS/DMHC Medical Review Audit	YE 08/31/00
Department of Managed Health Care (DMHC)	DMHC and DHS/DMHC Medical Review Audit	YE 08/31/00

Chief Executive Leadership Approval *		
Title	**Signature**	**Date Approved**

Chief Executive Officer		
Chief Medical Officer		
Choose an item.		
Choose an item.		
*Signatures are kept on file for reference but will not be on the published copy		

KERN HEALTH SYSTEMS

Policy and Procedure Review

KHS Policy & Procedure: 13.01-P Drug Utilization and Non-Formulary Treatment Request

Last approved version: 2023-07

Reason for revision: Per annual routine review, a purpose statement was added.

Director Approval		
Title	**Signature**	**Date Approved**
Bruce Wearda Director of Pharmacy		

Date posted to public drive: _____

Date posted to website ("P" policies only): _____