KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES					
SUBJECT: Drug Utilization and Non-Formulary Treatment Request				POLICY #: 13.01-P	
DEPARTMENT: Pharmacy					
Effective Date: 08/1997	Review/Revised Date: 1/1/2023	DMHC	X	PAC	
		DHCS	X	QI/UM COMMITTEE	
		BOD		FINANCE COMMITTEE	

_____ Date _____
Emily Duran
Chief Executive Officer

_____ Date _____
Chief Medical Officer

_____ Date _____
Director of Pharmacy

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 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. All medically necessary outpatient prescription drugs, except for those specifically excluded from the Medi-Cal contract, shall be available to 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:

- Code of Federal Regulations Title 42 §§431.211; 431.213; and 431.214
- California Health and Safety Code §§ 1367.01[2]; 1367.21; 1367.22; 1367.24
- California Welfare and Institutions Code §14185
- CCR Title 28 §1300.67.24
- CCR Title 22 §§ 51003; 51014.1; 51014.2; 53854; 53894
- DHS Contract Exhibit A - Attachment 5 (3)(F); Exhibit A –Attachment 10 (7)(F)
- 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]

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.

PROCEDURES:

1.0 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. (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

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

A. Patient name.
B. CIN number.
C. Diagnosis with brief history.
D. Reason for request/justification including formulary medication failures.
E. Drug name, strength, directions, and National Drug Code.
F. Prescriber's name.

2.0 REVIEW OF TAR

Incoming requests are date and time stamped. TAR review includes the actions outlined in

the following table.

Action	Timeline	Comments
Review by Pharmacist or 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 on the basis of appropriateness, efficacy, safety, pharmacokinetics and cost effectiveness.

3.0 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[9] (within 24 hours of receipt). [10]	
Denied	Denied form (within 24 hours of receipt).[11]	*Notice of Action Documents* (within 2 business days of the decision). [12] Documents include all of the following: ❖ *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 of the required elements for both provider and member notice of delay, denial, or modification including the following[13]:

A. The action taken.
B. A clear and concise explanation of the reason for the decision (including clinical reasons for decisions regarding medical necessity).
C. A description of the criteria/guidelines used.
D. A citation of the specific regulations or plan authorization procedures supporting the action[14].
E. Information on how to file a grievance with KHS including the Plan's name address and phone number.
F. Information regarding a Medi-Cal member's right to a State Fair Hearing including:

1. The method by which a hearing may be obtained.
2. 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.
3. The time limit for requesting a fair hearing.
4. The toll-free number for obtaining information on legal service organizations for representation.

G. Nondiscrimination Notice.
H. Language Assistance Taglines.
I. Information regarding the member's right to an Independent Medical Review with DMHC.
J. DMHC required language regarding grievances[15].
K. Name and telephone number of the pharmacy department.

4.0 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.*[16]

5.0 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.

5.1 Emergency Supplies[17]

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[18]. 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.

6.0 CONTINUITY OF CARE[20]

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[21] If previously approved by plan immediately prior to the date of enrollment, coverage may be continued until the prescribed therapy is no longer prescribed by a contracting practitioner[22]. 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.

7.0 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.

8.0 OFF-LABEL USE FOR LIFE THREATENING OR CHRONIC AND SERIOUS CONDITIONS[24]

8.1 Medi-Cal Product

Section does not apply to the Medi-Cal product.[25]

8.2 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 Centers for Medicare and Medicaid Services as part of an anticancer chemotherapeutic regimen:

(1) The Elsevier Gold Standard's Clinical Pharmacology.
(2) The National Comprehensive Cancer Network Drug and Biologics Compendium.
(3) The Thomson Micromedex DrugDex.

C. 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[26].

9.0 SAMPLE MEDICATIONS[27]

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*.

10.0 TRIAL PERIOD[28]

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.

11.0 MONITORING[29]

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.

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

REFERENCE:

Revision 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.**;** [1]**Revision 2021-07:** Policy revised by Director of Pharmacy regarding changes in pharmacy authorizations and billing. **Revision 2020-02: Revision 2017-07:** Policy revised to comply with CMS Final Rule on prior authorization process. Attachments updated. **Revision 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. **Revision 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. **Revision 2014-04:** Language included in Section 1.0 to add time statement on authorization request. Revised to remove references to Health Families product. **Revision 2013-07:** Reviewed by Director of Pharmacy. Routine revision, updated Section 1.0 regarding submission of treatment authorization request. **Revision 2009-10:** Revision requested by Director of Pharmacy. **Revision 2009-02:** Revised to comply with MMCD Policy Letter 08-013. Notice of Action letters updated with language assistance services notice. **Revision 2007-05:** Revised per DHS/DMHC Medical Audit comment 5/13/2007. **Revision 2007-04** Created Notice of Action Letters for Healthy Families product line per DHS/DMHC Medical Review Audit (YE 10/31/06). **Revision 2005-07:** Reviewed against MMCD Letters 04006 and 05005. New NOAs. **Revision 2005-04:** Continuity of care processes reviewed and revised. Reviewed against DHS Contract 03-76165 (Effective May 1, 2004). **Revision 2004-05:** Revised per DMHC/DHS Medical Audit YE Oct03; finding 1.2. (Addition of member notice of modifications). New single letter for deferral, modification, or denial. **Revision 2002-03**: Revised per DHS comment 01/30/02. **Revision 2002-01:** DHS CAP Verification Visit Report (Med Rev YE 08/00). **Revision 2001-02**: changes made for 2000 Legislation submission – DMHC and DHS/DMHC Medical Review Audit (YE 08/31/00).

[1] HSC 1367.24. CCR Title 22 §53854(d), CCR Title 28 1300.67.24
[2] Applicable to pharmacy per Title 28 §1300.67.24(a)(1)
[3] HSC §1367.01(b)
[4] HSC §1367.21(e)
[5] HSC §1367.21(d)
[6] HSC §1367.01(g)
[7] MMCD Policy Letter 08-013
[8] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 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))
[9] Must include specific service approved (HSC §1367.01(h)(4))
[10] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 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.
[11] Social Security Act, Title XIX, Section 1927(a)(5). Per John Kaylen at DHS, allows an extension from 24 hours to 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))
[12] 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)
[13] HSC §1367.01(h)(4) and (5) and 1367.24(b); CCR Title 22 §53894
[14] Required for member notice only. CCR Title 22 §53894(d)(3)
[15] Required for member notice only. HSC §1367.24(b)
[16] DHS Contract 03-76165 Exhibit A – Attachment 5 (2)(G)
[17] CCR Title 22 §53854(2)
[18] Title 22 51056
[19] Title 22 51056
[20] HSC 1367.22
[21] HSC § 1367.22
[22] W&I Code 14185(c)
[23] HSC §1367.22
[24] Health and Safety Code §1367.21
[25]Plan shall reserve the right to modify this. [26] HSC 1367.21 (b)
[27] Section added upon request of the Director of Pharmacy (3/2/05). Language also included in *Policy 2.24 – Pharmaceutical Guidelines*
[28] Section added upon request of the Director of Pharmacy (3/2/05).
[29] DHS/DMHC Medical Review Audit (YE 10/31/06).