KERN HEALTH SYSTEMS

Policy and Procedure Review/Revision

Policy 13.04-I Formular Process and Drug Utilization Review has been updated and is provided here for your review and approval.

Reviewer	Date	Comment/Signature
Doug Hayward	7/23/21	
Dr. Tasinga	7/21/2021	M Tasinga
Bruce Wearda	7/19/2021	**Bruce Wearda**

(CEO decision(s))

Board approval required: Yes ___ No ____ QI/UM Committee approval: Yes ___ No ___
Date approved by the KHS BOD: _____ Date of approved by QI: _____
PAC approval: Yes ___ No ___ Date of approval by PAC: _____
Approval for internal implementation: Yes ___ No ___
Provider distribution date: Immediately _____ Quarterly _____

Effective date: _____
DHCS submission: _____
DMHC submission: _____
Provider distribution: _____

KERN HEALTH SYSTEMS

KERN HEALTH SYSTEMS POLICY AND PROCEDURES					
SUBJECT: Formulary Process and Drug Utilization Review				POLICY #: 13.04-I	
DEPARTMENT: Pharmacy					
Effective Date: 07/2000	Review/Revised Date: 07/23/2021	DMHC		PAC	
		DHCS	X	QI/UM COMMITTEE	
		BOD	X	FINANCE COMMITTEE	

_____ Date _____
Douglas A Hayward
Chief Executive Officer

_____ Date _____
Chief Medical Officer

_____ Date _____
Director of Pharmacy

POLICY[1]:
The following will be in effect until the launch of Medi-Cal Rx (MCRx). Until that time, these policies and protocols effectuated by Kern Health Systems (KHS) will remain unchanged and in place.[(2)] At the time that MCRx assumes operations, the following will no longer be operated by KHS: This introduction paragraph, sections 1 – 4, section 5.1.1, prospective DUR, and attachments A and B. At this point section 5.1.2 will then be reviewed by the current MCRx parameters.

Kern Health Systems (KHS) will maintain a Therapeutic Formulary for the purpose of delineating specific prescribed treatments (medcations, durable medical equipment, etc.) that are felt to be the most therapeutically efficacious and cost effective. The formulary process is intended to facilitate the prescribing practices of contracted providers while also being used as a tool for budgeting pharmacy benefits, purchasing, and monitoring usage of prescribed treatments.

[3]The KHS formulary shall be comparable to the Medi-Cal FFS list of contract drugs, except for drugs carved out through specific contract agreements. The KHS formulary shall contain drugs which represent each mechanism of action sub-class within all major therapeutic categories of prescription

drugs included in the Medi-Cal FFS list of contract drugs. The KHS formulary will not necessarily include all drugs listed on the Medi-Cal FFS list.

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

- California Health and Safety Code §§ 1363.01 and 1367.20
- DHCS Contract Exhibit A – Attachment 10 (F)

KHS shall develop and implement effective drug utilization reviews and treatment outcomes systems to optimize the quality of pharmacy services.[4]

PROCEDURES:

1.0 SUPERVISION OF THE FORMULARY PROCESS

The Board of Directors, (the Board), is ultimately responsible for supervising the formulary process. This responsibility is delegated, with certain restrictions, to the Pharmacy and Therapeutics Committee.

2.0 FORMULARY APPROVAL

The Board will approve the entire Therapeutic Formulary on a yearly basis. The submission of the Formulary for approval is the responsibility of the Chief Medical Officer or their designee. The submission should include a summary of actions regarding the Formulary taken over the preceding year.

3.0 FORMULARY REVIEW

The KHS Formulary is reviewed and updated no less than quarterly.[5] This review and update considers all drugs approved by the FDA and/or added to the Medi-Cal Fee-For-Service list of contract drugs.[6]

The Pharmacy and Therapeutics Committee, (the Committee), will be responsible for reviewing specific medications and treatments for possible inclusion in or deletion from the Formulary. Deletions to the formulary are documented and justified.[7]

The Committee will periodically review elements of the Formulary with the intent of keeping it up-to-date. All therapeutic categories should be reviewed every two years.

3.1 Criteria and Methods

The following criteria and methods will be used for reviewing specific treatments for new or continued inclusion on the Formulary: (Attachment A of this Policy and Procedure is a sample "Formulary Addition Review" worksheet. Attachment B of this Policy and Procedure is a sample "Formulary Addition/Deletion Form" to be submitted by contracted providers for consideration.)

Criteria: Therapeutic efficacy
Methodology: Clinical literature will be accumulated addressing the efficacy of a medication or treatment. Examples of literature sources would include medical journals, the Medical Letter, pharmacology journals, and agency bulletins, professional society's guidelines.

Criteria: Cost effectiveness
Methodology: When available, reliable sources will be sought to determine the cost effectiveness of a specific treatment. These sources can be drawn from the literature or from the experience of other organizations with similar membership.

Considerations may include the projected cost per equivalent dose of a medication (i.e. therapeutic equivalence), the potential for improved compliance by patients, and the possible reduction in hospitalizations and/or other resource use.

Criteria: Safety
Methodology: Almost every medication has risk factors attached to it. These risk factors include adverse reactions, drug interactions, abuse potential, etc. Medications reviewed by the Committee will be examined for safety in the formulary process.

Criteria: Community Standard of Care
Methodology: The experience of the members of the Committee will be drawn upon to determine the Community Standard of Care regarding a specific treatment or disease entity. The Committee may call upon a recognized specialist for an opinion as well.

Criteria: Prior Utilization Patterns
Methodology: Utilization patterns for an existing medication or a proposed addition to the Formulary will be evaluated using the pharmacy claims database. This methodology may help determine a community standard of care and/or the cost effectiveness and potential costs of a treatment.

Criteria: Specific Requests
Methodology: Providers or members may request that the Committee consider a particular medication or treatment for inclusion on or deletion from the Formulary. By contract with the Department of Health Services the Formulary must include the same therapeutic categories as the Medi-Cal Formulary. Specific medications may be mandated for inclusion on the Formulary as the result of either existing or future statues and regulations. By contrast, the same contract may prohibit or carve out specific medications or therapeutic classes of medications.

Criteria: Restrictions
Methodology: The Committee may include recommendations for specific restrictions for particular medications such as restrictions to certain diagnoses, patient age, prior use of other medications and a limit on the amount of medication over a certain period of time. Other parameters for prescribing such as the maximum number of doses dispensed, the maximum number of prescriptions permitted, the frequency of refills and the number of refills that may be dispensed over a given time period.

Criteria: Dosage Forms
Methodology: The Committee recommendation may include limited dosage forms for each medication. Unless specified, the recommendation will include all dosage forms.

3.2 Report of Recommendations

After review by the Committee, a report will be made by the Chief Medical Officer or by the Director of Pharmacy at the next Board meeting including the recommendations of the Committee. The report will include a summary of the evaluation of the

treatment relative to the specific criteria delineated in Section 3.1. The Board will either approve, modify or reject the recommendations regarding the following categories and may return them to the Committee, either with or without instructions, for further review.

A. New medication categories
B. More expensive medications within an approved therapeutic class
C. Policy and Procedure recommended by the Committee
D. Incentive and disincentive programs
E. Market share programs
F. Rebate – Grant programs

The following additions/changes to the formulary will not require approval from the Board prior to addition to the Formulary:

A. new strength of an approved medication
B. A new medication in approved therapeutic category that is directly less expensive than the existing medication in that category

The committee's recommendation shall include recommended dosage forms for each medication and may include recommendations for specific restrictions for particular medications such as restrictions to certain diagnoses, patient age, prior use of other medications and a limit on the amount of medication over a certain period of time. The Board's action on the recommendation should be limited to review of the medications and not the dosages or restrictions.

4.0 MEMBER EDUCATION AND AVAILABILITY TO THE PUBLIC

The *Member Handbook* includes notice regarding the KHS Formulary and the formulary process. Information in the *Member Handbook* includes, but is not limited to, an explanation of what a formulary is, how KHS determines which prescription drugs are included or excluded, and how often KHS reviews the contents of the formulary. [8]

KHS provides to members of the public, upon request, information regarding whether a specific drug or drugs are on the KHS Formulary. Notice of the opportunity to secure this information from KHS, including the telephone number for making a request of this nature, is included in the *Member Handbook*.[9]

KHS notifies members, and members of the public who request formulary information, that the presence of a drug on the KHS Formulary does not guarantee that a member will be prescribed that drug by his or her prescribing provider for a particular medical condition.[10]

KHS provides to members of the public, upon request, a copy of the *KHS Formulary*. The provided formulary will include the most current list of formulary prescription drugs by major therapeutic category, with an indication of whether any drugs on the list are preferred over

other listed drugs. If KHS maintains more than one formulary, KHS will notify the requester that a choice of formularies is available.[11]

5.0 DRUG UTILIZATION REVIEW

The Committee will review other parameters for prescribing such as the maximum number of doses dispensed, the maximum number of prescriptions permitted, the frequency of refills, and the number of refills that may be dispensed at one time. The Committee will make recommendations regarding these parameters to the Board on a periodic basis.

KHS conducts drug utilization reviews. [12] The Committee will monitor the prescribing patterns of contracted providers. It will also review any quality of care issues that may arise as they pertain to the prescribing and dispensing of medications.

The Committee will report to the Quality Improvement/Utilization Management Committee any situations that may indicate substandard quality of care. Such reports shall be maintained as confidential peer review committee records.

5.1 DUR COMPONENTS[13]

KHS's DUR program contains:

- **5.1.1** A prospective DUR process.
- The PBM handles this by incorporating various point of sale edits at the dispensing location. Some edits are soft with messaging. Others are hard edits, again with messaging and would require prior authorization for overriding. Some of the Safety and Utilization edits are:
    - Utilization: 80% completion factor for non-controlled medications, 85% completion factor for controlled substances.
    - Early fill/refill.
    - Maximum day supply for chronic medications is 60 days. Acute medications are limited to 30 days.
    - DUR Safety edits block for therapeutic duplication/contraindications as well as drug-drug interactions. (ie: DPP-4/GLP-1, PPI/H2, opioids/benzodiazepines, opioids/antipsychotics.)
    - MEDD: limit 120
- **5.1.2** A retrospective DUR process. (After the transition and DHCS assumes operations, these will be reviewed using the current DHCS parameters.)
    - Utilization: 80% completion factor for non-controlled medications, 85% completion factor for controlled substances.
    - Early fill/refill.
    - Maximum day supply for chronic medications is 90 days. Acute medications are limited to 30 days.
    - DUR Safety edits block for therapeutic duplication/contraindications as well as drug-drug interactions. (ie: DPP-4/GLP-1, PPI/H2, opioids/benzodiazepines, opioids/antipsychotics.)
    - MEDD: limit 120

- Trends of claims are reviewed monthly. Instances of therapeutic duplications or contraindications are monitored.

- Instances of inappropriate concurrent use of opioids and antipsychotics and other combinations as identified by HR 6, The SUPPORT ACT, are identified by review of pharmacy claims.
- Participation in the DHCS' DUR Board and other DHCS organized pharmacy committee meetings.
- Education programs and resources to network providers and pharmacies.
- An annual report to DHCS detailing KHS' DUR activities.

Recommendations from the DHCS DUR Board will be shared with KHS P&T Committee. It will vote to accept or reject those recommendations. These votes will be summarized and provided in the annual report to DHCS.

6.0 REPORTING

6.1 A report of changes to the formulary is submitted to DHCS upon request and on an annual basis.[14] Pharmacy service and drug utilization encounter data are provided to DHCS on a monthly basis.[15]

6.2 A report of KHS' DUR activities is submitted to DHCS on an annual basis, allowing DHCS to compile and submit a single, annual Medi-Cal DUR report in compliance with Newly Revised Medicaid Drug Utilization Review Annual Report Survey.[16]

ATTACHMENTS:

- Attachment A - *Formulary Addition Review* Worksheet
- Attachment B—Request for Addition or Deletion of a Drug to the Formulary

REFERENCE:

[1] **Revision 2021-07:** Policy revised to comply with APL 19-012. Section 5.1 DUR Components; revised by the Director of Pharmacy. Revision 2019-09: Policy reviewed and updated by Director of Pharmacy. KHS address updated to new location in attachment B. **Revision 2017-06:** Policy revised to comply with APL 17-008. Policy approved by DHCS 6/12/2017 as part of the Final Rule Deliverables. **Revision 2014-11:** Minor revisions provided by Director of Pharmacy. Policy will be presented to the KHS Board of Directors. **Revision 2013-10:** Policy reviewed by Director of Pharmacy. No revisions needed at this time. **Revision 2005-11:** Routine revision. Policy reviewed against DHS Contract 03-76165 (Effective 5/1/2004). (EO) N-01-19, APL 02-020

[2] Director of Pharmacy made change due to Medi-Cal Rx (MCRx)

[3] DHS Contract A-10 (F)(2)[4] DHS Contract A-10 (F)(1)

[5] DHCS Contract A-10 (F)(3)

[6] DHCS Contract A-10 (F)(3)

[7] DHCS Contract A-10 (F)(3)

[8] HSC §1363.01 (a)

[9] HSC §1363.01 (b)

[10] HSC §1363.01 (c)

[11] HSC §1367.20

[12] DHCS Contract A-10 (F)(4)

[13] DHCS Contract A-10 (F)(2)

[14] DHCS Contract A-10 (F)(2)

[15] DHCS Contract A-10 (F)(4)

[16] DHCS APL 17-008 (May 10, 2017)

Formulary Addition Review

Medication:	
Generic Name	
Brand Name (Manufacturer)	
Legend or OTC	
Indications	
Time on market	
Drug Class:	
Drug Class	
New Class?	
Similar drugs on Formulary	
Similar drugs not on Formulary	
Drugs that me be replaced	
Advantages/Disadvantages:	
Advantages	
Disadvantages	
Chronic or Acute use	
References:	
Medical Letter/Society guidelines	
Other	
Formulary Status	
Recommendations:	
Add to Formulary	
Code Restrictions	

Financial Analysis:	
Historic Drug Class Costs	
Current Rx's in Class per year	
Projected cost per Rx	
Typical cost per Year	
Historic cost of replaced drugs	
Other Impact (Lab, ER visits, etc.)	
Budget Impact Estimate:	

P&T Committee Review Date(s):

Board Presentation Date:

Comments:

Board Action:

Kern Family Health Care
The Friendly Face
Of Kern Health Systems

REQUEST FOR ADDITION OR DELETION OF A DRUG TO THE FORMULARY

Generic Name: _____ Brand Name: _____

Manufacturer(s): _____

Dosage Form: _____

Pharmacological Classification: _____

Indications: _____

What similar drugs are currently available? _____

_____

What therapeutic advantage(s) does this drug have over the standard drug therapy? _____

_____

In how many patients do you expect this drug to be used during the next six months? _____

_____

What drug(s) currently used for this/these indications(s) may be deleted if this product is added to the formulary? _____

_____

Should use of this drug be restricted to certain physicians or institutions because of the potential for misuse, high cost, or toxicity? _____

_____

Please list any conflicts of interest or connections to the manufacturer: _____

_____

Requesters Name: _____

Address & Telephone: _____

Signature of Requester: _____ Date: _____

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