HEALTH PLAN OF SAN JOAQUIN					
Subject: Formulary System Management					
Department: Medical Management	**Unit:** Pharmacy			**Policy #:** PH01	
Effective Date: 09/18/2012	**Committee/Approval Date:** P&T 09/12/2017	**Review/Revision Dates:** 11/14, 09/15, 09/16, 09/17			
Applies To:	Medi-Cal	Yes	**X**	No	

POLICY

The Health Plan of San Joaquin (HPSJ), under the auspices of the P&T Committee, maintains a formulary of preferred medications and appropriate prescribing guidelines and other pharmaceutical management procedures for the treatment of its members. HPSJ maintains an ongoing process to evaluate and recommend policies and procedures on the use of drugs and related products to optimize patient care and cost effectiveness for its membership through rational selection.

PROCEDURE

A. The Formulary System consists of:

1. A Drug Formulary or Preferred Drug List (applicable to each product or product line).
2. Comprehensive policies and procedures addressing all aspects of the Formulary System.
3. Information for practitioners and members, including:
    a. How to use pharmaceutical management procedures.
    b. An explanation of Quantity Limits.
    c. Processes for:
        i. Prior Authorization.
        ii. Generic Substitution.
        iii. Step Therapy.
        iv. Therapeutic Interchange.
        v. Non-Formularyrequests.
    d. How to provide information to support a Prior Authorization request.
    e. How to provide information to support an Exception request.

f. How to provide information to support a request for exemption from a Pharmaceutical Management Process.

4. Processes for patient safety including:

a. Point of dispensing communications regarding drug-drug interactions, contraindications, and therapeutic duplications.

b. Notification of drug recalls and withdrawals.

5. Processes to communicate with, and educate practitioners and members on, pharmaceutical issues.

B. Decisions regarding the Formulary System are based on scientific evidence, standards of practice, and economic considerations that include:

1. Peer-reviewed medical literature including randomized clinical trials, pharmacoeconomic studies, and outcomes research.

2. Published practice guidelines promulgated by recognized organizations and based on a sound evidence-based process.

3. Comparing the efficacy and types and frequencies of side effects and potential drug interactions among alternative drugs.

4. Assessing the likely impact on patient compliance of one drug product compared to alternatives.

5. A thorough evaluation of the benefits, risks, and potential outcomes for patients.

6. Considering cost factors only after safety, efficacy and therapeutic need have been considered.

7. Evaluating financial impact in terms of the impact of Formulary System decisions on total health care costs.

8. Pharmacologic considerations such as:

a. Drug class.

b. Similarity to existing drugs.

c. Side effect profile.

d. Mechanism of action.

e. Therapeutic indications.

f. Drug-drug interaction potential.

g. Clinical advantages and risks and benefits relative to other products in the specific drug class.

h. Off-label uses and their appropriateness.

i. Bioavailability data.

j. Pharmacokinetic data.

k. Dosage ranges by route and age.

8. Consideration of patient demographics.
9. Consideration of risk factors relative to:
    a. Contraindications.
    b. Warnings.
    c. Precautions.
    d. Potential for abuse and misuse.
10. Special monitoring or drug administration requirements.
11. Pharmacy reports, including:
    a. Current utilization patterns.
    b. Monthly drug reviews.
    c. Therapeutic class reviews.
    d. Market share and trend analysis.
    e. Non-formulary utilization patterns.

C. The Pharmacy Department clinically and administratively supports the P&T committee and is responsible for implementing the Formulary System and managing pharmacy benefits.

D. The Pharmacy Department seeks and receives data and information regarding pharmacy and medical issues and utilization from various internal and external sources to evaluate the impact changes in the medical community may have on HPSJ's pharmacy utilization.

E. The Pharmacy Department gathers data and information from a broad range of resources to facilitate the presentation of relevant pharmacy and benefit issues to the Committee for action and recommendations. These resources include, but need not be limited to:

1. Professional pharmacy associations.
2. Medical associations.
3. National commissions.
4. Relevant government agencies.
5. Peer reviewed journals.
6. Authoritative compendia including, but not limited to:
    a. Micromedex.
    b. The American Society of Health System Pharmacists.
    c. The Academy of Managed Care Pharmacy (AMCP).
    d. Facts and Comparisons.
7. The contracted PBM.

F. When reviewing the information sources described above, the primary focus is on:

1. Meaningful clinical outcomes data from peer-reviewed clinical trials.
2. Safety and efficacy data from peer-reviewed clinical trials and from sources such as AMCP dossiers, PubMed, Micromedex, and Facts and Comparisons.
3. Similar data from unpublished clinical trials, where sufficient information is available to evaluate the quality of the evidence provided.
4. FDA approval information and FDA product reviews.
5. Peer-reviewed meta-analyses and articles from sources such as AMCP dossiers, PubMed, Micromedex, and Facts and Comparisons.
6. Studies examining health status measures and quality of life.
7. Information demonstrating significant improvements in patient compliance and acceptability.
8. Pharmacoeconomic studies evaluating the cost-effect, cost-utility and/or cost benefit of a pharmaco-therapeutic treatment in a given setting and patient population generalizable to the HPSJ population.
9. Information, guidelines, and recommendations from credible external organizations which include their clinical rationale and the supporting documentation for their recommendations.

G. A clinical pharmacist reviews regular and ad hoc reports to look for trends in HPSJ's drug utilization.

1. Collected data are analyzed by the clinical pharmacist to identify current and potential utilization trends and practices that could impact patient safety, treatment efficacy, and pharmaceutical usage including:
    a. Potential increases in utilization due to drug manufacturer promotion of new drugs and/or drugs with new indications to the public and practitioners.
    b. Therapeutic appropriateness of prescribed medications and therapeutic duplication in treatment regimens.
    c. Patients receiving medication for duration of treatment that varies from the norm.
    d. Changes in drug and/or drug class utilization due to increased use of newer drugs over established safe and effective therapies.
    e. Increased prescribing of drugs by practitioners, including:
        i. The unnecessary use of multiple drugs to treat a single medical condition.
        ii. The use of new or biologic medications instead of, or as a supplement to, preexisting clinically effective therapies.
        iii. Increased use of narcotic agents to treat patients that may be better served with case management or alternative therapies

e. Drug mandates by governmental entities affecting the coverage of specific drugs and/or drug classes.

f. The effects on drug class utilization due to the availability of clinically proven generic medications.

H. Quality Improvement Process for Clinical

I. All therapeutic and pharmaceutical classes and pharmaceutical management policies will be reviewed annually by clinical pharmacy staff with the participation of local physicians and pharmacists via the P&T Committee.

1. Utilization patterns, clinical guidelines and recently published trials will be taken into consideration.

2. Covered drugs, pharmaceutical procedures, limits, restrictions, and quotas will be reviewed for appropriateness.

3. The list of pharmaceuticals covered and pharmaceutical management procedures will be updated as appropriate.

4. Policies will be reviewed by the Director of Pharmacy annually for opportunities for improvement. Recommended changes are brought to the P&T committee for review and approval.

5. Drugs or drug classes are considered for pharmaceutical management when the review described above identifies the drug or drug class as having the potential to pose a significant clinical or cost impact to HPSJ.

J. Committee input and recommendations are sought when looking to choose which pharmaceutical management approach to apply.

K. When making decisions about which pharmaceutical management procedures to employ, the Committee considers:

1. Drug characteristics, such as efficacy and safety.

2. The medical condition being treated.

3. Affected patients.

4. Government regulations.

5. Standards of care.

6. Economic impact.

L. In its decisions regarding pharmaceutical management procedures, the Committee strives to:

1. Develop a Drug Formulary which favors drugs that have been determined to be the most clinically appropriate, safe, and cost-effective drugs for the diagnosis and treatment of disease and promotion of health.

2. Recommend Generic Substitution when doing so will not affect therapeutic efficacy.

3. Set Quantity Limits based on treatment duration or maximum dosing limits as approved by the FDA or as reflected in current authoritative sources to ensure patient safety.

4. Identify drugs and drug classes where drug tiers can influence member utilization and provider prescribing toward the use of more cost effective alternatives.

5. Implement Step Therapy protocols when there is a recognized first line drug that should be used before a second-line drug to foster safe and effective treatment while reducing the cost of treatment.

6. Recommend Prior Authorization requirements for drugs and drug classes with the potential for significantly increasing costs without a commensurate improvement in efficacy or health status.

7. Recommend Therapeutic Interchange when evidence suggests that outcomes can be improved by substituting a drug that is therapeutically equivalent but chemically different from the prescribed drug

8. Develop clinically sound criteria for reviewing requests for coverage of non-formulary drugs based on clinical circumstances and medical necessity.

9. Provide a mechanism to permit clinically appropriate exceptions to pharmaceutical management procedures.

M. Notifications to members and providers regarding pharmaceutical management procedures:

1. All changes to Pharmaceutical Management procedures listed in this document are updated on the website immediately after the change.

2. Quarterly Member and Provider Newsletters notify their recipients that Pharmaceutical Management procedures and any changes made are available on the website.

3. Providers will be notified in writing (e.g., letter, fax, email) annually and within 30 days of any changes to the provider manual (where explanation of pharmaceutical management procedures is available to them)

4. Members will be notified in writing (e.g., letter, fax, email) annually and within 30 days of any changes to the Evidence of Coverage (where explanation of pharmaceutical management procedures is available to them)

5. Members and providers directly affected by changes will be notified by fax/mail no less than 30 days before the change takes effect.

N. Quality Improvement Process for Formulary and Coding Accuracy

1. Effective 7/1/2015, at least once every 6 months, the following will be systematically evaluated by HPSJ pharmacy staff:

a. Accuracy of the PBM coding of the intended formulary setup. This may include (but is not limited to):

i. Reports of the filled and rejected claim history for all drugs affected by formulary changes in the last 12 months

ii. Reports of all rejected claims in the last 12 months and rejection reasons

b. Accuracy of the online formulary and website compared to the intended formulary setup. This may include (but is not limited to):

i. Spot check of random selection of 1% of the formulary (~50 drugs) for online formulary accuracy compared with intended setup

ii. Review of online formulary status for all drugs affected by formulary changes in the last 12 months

iii. Review of online Pharmacy Benefit section of website for accuracy and checking of links/resources to ensure they are in working order

iv. Audit of pharmacy related Member Services calls for errors in benefit or online formulary setup

2. At least one report in each of the two categories will be evaluated every 6 months and reported to the P&T committee along with corrective action plan (if necessary).

O. Participating providers may request changes to the Drug Formulary by contacting HPSJ in writing at:

Health Plan of San Joaquin
Attn: Director of Pharmacy
7751 S. Manthey Road
French Camp, CA 95231-9802

REFERENCE

A. NCQA Standard UM13 – Procedures for Pharmaceutical Management

Health Plan of San Joaquin
Approval: Signatures on File

DHCS Contract Deliverables

Contract Reference	*Date of Approval*	*DHCS Unit*		*Contract Reference*	*Date of Approval*	*DHCS Unit*
A.18.10						