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Policy Title: Pharmacy Program Description	Policy Number: NW.UM 13C
Owner Department: Pharmacy	Effective Date: 03/2004
Custodian: Emily Thomas, PharmD	Last Review / Revision Date: 07/2024
Approver: Utilization Review Oversight Comm.	Next Review Date: 07/2025
Review Period: 1 Year	Page: 1 of 6

1.0 Policy Statement

The Regional Pharmacy Department uses an integrated, electronic delivery system to serve the Kaiser Permanente Northwest (KPNW) region from Eugene, Oregon to Longview, Washington, with 29 pharmacy locations available to serve over 600,000 members and fill more than 5 million prescriptions annually.

This policy applies to all pharmaceuticals, whether the pharmaceutical is covered under the medical benefit or pharmacy benefit.

2.0 Purpose

Medication *safety, efficacy and cost* are the core values of the KPNW Pharmacy Department. These values are applied at monthly meetings of the Regional Formulary and Therapeutics Committee (RFTC) through *"evidence-based"* decision making. These decisions are implemented by the Clinical Pharmacy Services department with operations staff assistance down to the clinic pharmacy level. Formulary decisions, drug initiative strategies, and Pharmacy Department policies & procedures are made available to all pharmacy, health plan and medical staff via several communication methods, including postings on the Pharmacy Department internal website and electronic mail distributions. As a result, the pharmacy program and all elements of pharmacy service delivery support the mission of Kaiser Permanente.

The RFTC maintains policies and procedures for pharmaceutical management as a framework to guide safe, effective and cost-conscious medication management in each therapeutic area. KPNW regional clinical targets help shape the development of pharmaceutical management procedures. The use and development of policies ensure consistent application of the procedures and support contractual obligations to KPNW members. The review of pharmacy policies and procedures is an ongoing process, with all policies reviewed at least annually and updated as appropriate.
To facilitate consistent application of the RFTC's formulary decisions and drug initiative strategies, approved criteria and therapeutic messaging is programmed into the electronic medical record and pharmacy computer system. These electronic systems are used by all clinicians, pharmacy and medical staff of KPNW. This enhances patient safety by allowing for real time communication between medical staff and pharmacy staff.

3.0 Scope/Coverage

3.1 This policy applies to all employees who are employed by the following entities:

3.1.1 Kaiser Foundation Health Plan of the Northwest (KFHPNW)

4.0 Definitions

Class 1 Drug Recall- removal of a distributed product due to reasonable probability that use of or exposure to the product will cause serious adverse health consequences or death.

Class 2 Drug Recall- removal of a distributed product where use of or exposure to the product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

Market Withdrawal- removal or correction of a distributed product which involves a minor violation that would not be subject to legal action by the Food and Drug Administration (FDA).

5.0 Provisions

5.1 Pharmacy Oversight & Administration

Responsibility for the development and review of pharmaceutical management policies is delegated to RFTC by the KPNW Regional Operations Quality Group (ROQG).

The RFTC membership is broad-based and includes practicing primary care physicians, hospitalists, pharmacist experts, and consulting specialty physicians. The RFTC meets monthly and implements the formulary process to support the successful attainment of Kaiser Permanente goals for rational, safe, effective and economical drug therapy in the Northwest Region.

5.2 Management of Pharmaceutical Policies & Procedures

The RFTC sponsors several subcommittees. Among them are the Regional Antibiotic Subcommittee, the Natural Products Advisory Committee, and the Immunization Practice Committee. The membership of these subcommittees includes physicians, pharmacists and other health care professionals [all subject matter experts in their given specialty area]. These subcommittees forward their recommendations to the RFTC for consideration. Approval and adoption follow the process described above.

The RFTC utilizes many medical expert resources to establish recommendations for safe and effective drug use within Kaiser Permanente. The regional Pharmacy Department functions independently but is interactive with other Kaiser Permanente regions. Examples of interregional cooperation include the sharing and development of drug monographs used by RFTC to make evidence-based medication determinations.

5.3 KPNW Formulary Process

The major responsibilities of the RFTC are the development of the KPNW Drug Formularies and the Therapeutic Equivalencies, as well as approval of medication related clinical content in the electronic medical record and any guideline that includes pharmaceutical agents. In developing the Formularies, the RFTC and the

specialists evaluate, appraise and select from all available drugs those considered to be *most* appropriate for patient care and general use in the KPNW region.

The Formularies are reviewed at least annually by the RFTC and updated as appropriate.

The RFTC promotes the use of the Formulary and therapeutic equivalencies utilizing direct communication and education to encourage and support clinician use of preferred drugs. The Pharmacy Department acknowledges the use of non-formulary drugs when deemed medically necessary by the prescribing clinician or when prescribing criteria is met. Non-formulary drugs excluded by contract are not covered but may be ordered.

When KPNW clinicians order a non-formulary drug that is not a criteria-based medication, there is a process to determine coverage, however this is not a requirement of the Utilization Management program. Ultimately, if a physician determines a non-formulary drug that is not criteria-based to be medically necessary and it is not excluded by contract, the clinician may order it for the member. If the non-formulary drug is determined to be medically necessary, the drug will be covered as specified by the member's pharmacy benefit.

When KPNW clinicians order a non-formulary, criteria-based medication, there is a specific process to determine coverage *[see UM Policy 13e: Criteria-Based Consultation Prescribing]*.

5.4 Pharmacy Communication to Clinicians and Members

All changes to the Formularies and Pharmaceutical Management policy or procedure are communicated to clinicians and members. This communication includes restrictions and preferred pharmaceuticals, an explanation of limits or quotas when applicable, how to use the pharmaceutical management procedures, the formulary exception process, how the prescribing clinician must support or provide information in support of a formulary exception request, and the processes for generic substitution, therapeutic interchange and step-therapy. The communication to clinicians and members includes a description specific enough to give readers a clear idea of the topic and the general content and includes a link to the specific information (for clinicians) or directions to the specific information (for clinicians and members).

KPNW clinicians are routinely notified via the Pharmacy Department website, electronic mail distributions and the electronic medical record. The Pharmacy Department website is an official communication channel and clinicians are notified what the website contains and how to access the site in their new hire packets. The Utilization Management department physician survey confirms clinician use of this communication method. External contracted clinicians are notified via a direct mailing annually and when changes are made to

pharmaceutical management procedures. External contracted clinicians have access to the KPNW Formularies via the community provider portal and the KPNW member website, kp.org.

Members are notified via the annually distributed Evidence of Coverage (member contract) and the annually distributed Medical Directory mailer on how to obtain or electronically access information regarding the prescription drug formulary process and the current Formularies. Members are notified via a member mailing if substantive changes are made to pharmacy procedures that affect their prescription drug benefit that were not included in their Evidence of Coverage.

5.5 Review of Management Policies, Procedures and Drugs

The RFTC is also accountable to oversee the ongoing review of Pharmaceutical Management policies and procedures and the evaluation of drugs for inclusion or removal from the drug Formularies. This monthly review includes but is not limited to:

- Annual review of existing formulary drugs
- Process of adding a drug to a formulary
- Process of deleting a drug from a formulary
- Process of communicating policies and procedures to practitioners annually and/or when a formulary is changed

5.6 Criteria used for Policy Development

Criteria for inclusion of a drug to the Formularies include, but are not limited to: demonstrated safety, measurable effectiveness, and affordability. Varied mechanisms and processes are used to execute these criteria.

5.6.1 **Safety**

- The RFTC process of evaluating medications allows for NOT adding medications that have high side effect profiles with risks that outweigh benefit.
- Safety alerts which occur at the time of dispense, allowing for immediate clinician notification.
- Known drug interactions and drug contraindications are monitored with the use of computer software programs that are continually updated.
- Ongoing review and monitoring of many pharmaceutical resources, including the FDA website for new or updated drug information including FDA directed withdrawals due to safety, contamination, manufacturing errors and mislabeling.
- Electronic Medical Record drug orders and individualized prescription histories are kept on electronic file and allow for member specific notification in the case of national drug withdrawals or other formulary process changes that would affect the member.

5.6.2 **Efficacy**

Efficacy is the demonstrated effectiveness of the drug in question for the indication for which it is prescribed. Effectiveness is determined by a thorough review of pertinent medical evidence, incorporating expert opinion and relevant findings from appropriate external organizations (e.g., Centers for Disease Control, National Institutes of Health, American Academy of Pediatrics, etc.).

- Medical evidence can include peer reviewed journal articles obtained through library searches and on-line search engines, as well as Kaiser Permanente Drug Information Services in other Kaiser Permanente regions.
- Expert opinion is obtained from practitioners who serve as consultants to the RFTC. Consultants may be invited to an RFTC meeting to present their opinions regarding the inclusion of certain medications on the Formularies, or they may present their opinions in writing or verbally communicate with a RFTC member.
- Relevant findings of appropriate external organizations are included in the monographs presented to the RFTC for consideration. Information is usually obtained via reliable sites on the internet or from peer reviewed journals.

5.6.3 **Cost**

Since effective use of the membership dollar is a primary Pharmacy Department value, the RFTC works with both Kaiser Permanente Regional and National Drug Purchasing departments to ensure Formulary drugs are safe, effective, and cost competitive. Methods of ensuring this include:

- Community based pricing strategies, allowing the KPNW Purchasing Department to monitor the pulse of retail community pharmacies to ensure we are within predefined limits.
- National contract and volume purchasing, allowing all Kaiser Permanente regions to optimize the health plan's ability to purchase large volumes of any given medication at a set price per unit for a determined contract period.

5.7 Pharmaceutical Procedures related to FDA Drug Recalls and Withdrawals

Members and prescribing practitioners affected by an FDA Class 1 or Class 2 drug recall or voluntary drug withdrawal from the market for safety reasons are notified within appropriate timelines:

5.7.1 Class 1 drug recall- within 14 calendar days
(Also see Pharmacy Drug Recalls Policy)

5.7.2 Class 2 drug recall or voluntary drug withdrawal from the market for safety reasons- within 30 days

6.0 Approval

This policy was approved by the following representative of Kaiser Foundation Health Plan of the Northwest and Kaiser Foundation Hospitals Northwest.

Signature: Kathy Fazio, RN _____ Date: 7/16/24
Utilization Review Administrator