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Policy Title: KPNW Formulary Process	Policy Number: NW.UM 13B
Owner Department: Pharmacy	Effective Date: 07/1996
Custodian: Emily Thomas, PharmD	Last Review / Revision Date: 07/2023
Approver: Utilization Review Oversight Comm.	Next Review Date: 07/2024
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1.0 Policy Statement

The Kaiser Permanente Drug Formularies are a compilation of drugs and drug supplies approved by the Regional Formulary and Therapeutics Committee (RFTC) for general use. The RFTC (refer to the *Constitution of the Regional Formulary and Therapeutics Committee*), with expert guidance from various specialists, evaluates, appraises and selects from available drugs those considered to be the most appropriate for patient care and general use within the Northwest region. The Formularies are published under authority of the RFTC.

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

2.0 Purpose

The Formulary process is intended to enhance the quality of patient care by ensuring that available drugs meet established quality standards by providing information for safe and effective use and by limiting the availability of drugs that are unsafe, less effective, and ineffective or have high potential for toxicity or abuse.

Formularies provide a vehicle for educating practitioners on the relative safety, medical appropriateness and cost-benefit of various drug therapies. It promotes use of effective but less costly therapeutic equivalents, reduces the number of therapeutically redundant drugs, maximizes leverage through the drug purchasing and bid process, and optimizes pharmacy management of drug inventories.

There are four outpatient drug formularies for the Kaiser Permanente Northwest Region: the Commercial Formulary, the National Medicare Part D (MPD) Formulary, the Oregon Marketplace Formulary, and the Washington Marketplace Formulary. (For additional policy related to the National MPD Formulary, refer to the National MPD Formulary Policies).

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

NA

5.0 Provisions

5.1 Formulary Drugs

5.1.1 Formulary drugs are drugs and biologic agents that have been reviewed by the RFTC and placed on the Formulary.

5.1.2 Non-formulary drugs are drugs which have not yet been reviewed or which were reviewed but not accepted for inclusion in the Formulary.

5.1.3 Therapeutic Equivalent drugs (TE) produce essentially the same therapeutic outcome and have similar toxicity profiles. These drugs are usually within the same pharmacological class or are different dosage forms of the same drug (i.e. tablet for capsule or half-tablet for full tablet of lesser strength).

5.1.4 KPNW does not employ incentives or penalties in order to influence clinician prescribing. KPNW does employee formulary education to encourage and support formulary prescribing.

5.1.5 Some drugs are restricted to use by one or more specialty physician groups or for use within the framework of a specific guideline. Restricted drugs are identified as such in the electronic medical record "medication orders" screen. Therapeutic messaging instructs the prescriber about the specific restriction.

a. Criteria for restriction may include:
   i. High potential for abuse.
   ii. High potential for adverse effects (significant side-effect profile).
   iii. High cost to benefit ratio in conjunction with other clinical concerns.

b. KPNW employs Criteria-Based Consultation Prescribing. *(See UM Policy 13e: Criteria-Based Consultation Prescribing* for more information).

5.2 Quantity Limits (QL) on certain drugs or supplies will apply upon dispensing to reduce wastage and ensure patient safety and appropriate use of drug supply. These limits are designed to identify the excessive use of drugs which may be harmful in large quantities, to highlight the potential need for a different type of treatment, and to match dosing recommendations/requirements set by the manufacturer and the FDA. QL may be considered for addition only if they meet one or more of the following criteria:

5.2.1 Drugs with approved or specific defined daily dose/frequency, or

5.2.2 Drugs with significant potential for diversion, or

5.2.3 Drugs with high costs and/or significant waste for specific strengths or package sizes, or

5.2.4 Drug shortage.

5.3 Drug Selection

5.3.1 Drugs are chosen for formulary review based on one or all of the following:

a. A practitioner requests review of a certain drug via *form 11.7 "*Drug Formulary Change Request Form*. "*

b. The drug represents a therapeutic class of drugs reviewed during an annual review of all formulary drugs.

c. The drug becomes generically available.

d. High rate of non-formulary use.

e. New information is available to support a change in current formulary.

NOTE: To assess post-marketing safety and effectiveness data, the committee may wait a few months after market entry to review a drug.

5.3.2 Drug selection decisions are made primarily based on safety and effectiveness. Safety and effectiveness are 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.). After safety and effectiveness are investigated, cost is considered.

a. 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. Medical evidence provides insight into the following:

i. Documentation of effectiveness

ii. Results and extent of clinical investigation

iii. Severity and incidence of toxicity and side effects

b. 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 formulary, or they may present their opinions in writing or verbally communicate with a RFTC member.

c. 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.

d. Additional information considered in making decisions include:

i. Availability of current formulary drugs to meet the therapeutic need
ii. Reliability and quality control of the drug manufacturer
iii. Current utilization of the drug by practitioners within the program
iv. Comparative cost of alternative equivalent therapy
v. Utilization of the Non-Formulary Exception Process (See Section D below*).*
vi. Other unique attributes which may warrant inclusion of the drug.

5.3.3 After the RFTC has reviewed the clinical evidence, expert opinion and other relevant information, a motion is made to add the drug to the Formulary, not add to the Formulary, to defer the decision awaiting further clinical information or, if applicable, to delete a drug from the Formulary. The decision is carried forth via parliamentary procedure and simple majority vote of the RFTC. Changes to the Formulary are not effective until they are posted on the internet the second Tuesday of the month following the meeting, unless otherwise specified.

5.4 Formulary Reviews

5.4.1 All therapeutic classes of medications are reviewed on an annual basis. Throughout the year, the RFTC periodically selects specific classes of drugs for review (e.g., antibiotics, antihypertensives, etc.). The review includes current Formulary products, existing non-Formulary alternatives and drugs which have recently been introduced into the market.

5.4.2 On an annual basis, the Medicare Formulary and the Marketplace Formularies are reviewed and approved in conjunction with the Commercial Formulary.

5.4.3 Any KPNW practitioner, pharmacist or member may request that a drug or dosage form be added to or deleted from the Formulary. Practitioner and pharmacist requests may be submitted in writing via form 11.7, “Drug Formulary Change Request Form” or via verbal communication to an RFTC member. Members requesting a formulary change will be directed to the Member Relations Department to submit a formal request that will be reviewed through the medical necessity determination process and, if approved, through the RFTC review process.

5.4.4 The RFTC evaluates the medical and pharmaceutical literature, discusses use of the drug with experts in the appropriate area of specialty, and may contact the requesting practitioner or pharmacist for additional information before discussing data and recommendations at the RFTC meeting.

5.4.5 The RFTC Staff communicates the committee's decision to the requesting practitioner or pharmacist within thirty days after the decision is made (See Section 5.5., below regarding communication).

5.4.6 The internal RFTC Actions document specifies effective dates for all formulary changes. This document generates changes to KP HealthConnect, ePIMS, Lexicomp, and the PBMs.

NOTE: Member requests are evaluated by their physician for medical appropriateness and may be prescribed via the Non-Formulary Drug Review Process. Should the physician deem a formulary exception is necessary, Section 5.4., Non-Formulary Drug Exception Process is followed.

5.5 Non-Formulary Drug Exception Process

5.5.1 Drugs not on the KPNW Formulary list are considered non-formulary, and are not covered by the drug plan co-pay or co-insurance, unless the prescribing clinician has determined the non-Formulary medication to be medically necessary.

5.5.2 The KPNW Regional Formulary and Therapeutics Committee sanctions the Non-Formulary Drug review process. The process is initiated by clinicians, pharmacy staff or members, and is overseen by Clinical Pharmacists, the RFTC Physician Chairman, and Pharmacy Department managers. (*See UM Policy 13a: Formulary Exception Process and Excluded Drug Review,* for additional information on the exception process).

5.5.3 The Non-Formulary Drug review process does not apply to drugs used for indications excluded by contract, drugs used for non-covered services, or drugs with criteria (see *UM Policy 13e: Criteria Based Consultation Prescribing & Step Therapy*).

5.5.4 The New Member Pharmacy Services Staff will conduct a telephone consultation and/or provide an electronic questionnaire for new members requesting prescription refills. New Member Pharmacy Services staff will obtain a medication history while helping members transition their medications into Kaiser Permanente. In consultation with the PCP selected by the member or their designee, the clinical pharmacist will help members maximize their pharmacy benefit and forward all data to the new PCP for future reference. Members may receive authorization for up to a 30 day supply of medication.

5.6 Availability of Formulary to Practitioners

5.6.1 The KPNW Drug Formularies are available to all clinicians and Health Plan staff via the internal KPNW Pharmacy Department website. Contract providers can access the Formularies via the kp.org website.

5.6.2 Physicians and Allied Health Plan staff are provided with information about the drug Formulary process upon employment. The New Clinician Packet also

includes information about Therapeutic Equivalency interchange and authorization, and other materials pertinent to the Pharmacy Department Formulary Management procedures.

5.6.3 A copy of the monthly RFTC meeting minutes, which includes drug summary rationale of formulary decisions, is distributed to all KPNW physicians and Allied Health Plan staff. The RFTC meeting minutes are also sent to all pharmacy department staff via electronic mail distribution.

5.6.4 The Formulary postings on the internal website (for employee use) and externally on kp.org are derived from the same system (Lexicomp) and are updated monthly to reflect changes made by the RFTC, including new drugs that are made available. Changes to the Formularies become effective the second Tuesday of the month following the meeting. Beginning 1/1/2021, negative formulary changes and any new utilization management restrictions become effective no sooner than 60 days following the meeting where change(s) were approved.

5.6.5 Updates are mailed to non-Northwest Permanente network clinicians/providers when substantive changes are made to processes and information not posted on the internet, and no less frequently than once per year.

5.7 Communication to Members

5.7.1 Both existing and prospective members are informed about the Kaiser Permanente Formulary Process via the Formulary process document, which includes information about how drugs are evaluated for formulary addition, and the criteria and process used to make those decisions. Members may access the Formulary on the internet via www.kp.org or request a paper copy of the Formulary list from a KPNW pharmacy or have a paper copy mailed.

5.7.2 Coverage determination of formulary or non-formulary medications or the extent of coverage is communicated to members.

a. Prospective members are informed through their enrollment materials and/or in-services provided by the sales and marketing representatives.

b. Existing members are informed through their Human Resources Department, or by calling Pharmacy Services. Also, verbal information about the Non-Formulary Exception Process is provided at the time a non-formulary medication request is initiated.

5.8 Applying the Formulary

5.8.1 Practitioners

a. All KPNW Physicians, Allied Health Providers and Plan Participating Providers who are licensed to prescribe pharmaceuticals in the state of Oregon or Washington may prescribe Formulary drugs without restriction.

b. Restricted medications are labeled as such in the Formulary and may be prescribed only by clinicians in certain specialties as designated in the Formulary.
   i. Clinicians within the specialty may prescribe the restricted product without special authorization.
   ii. Clinicians outside the designated specialty may only prescribe the restricted medication after consultation with a designated specialist. Upon specialist*'s* approval, the prescribing clinician orders the restricted drug and documents the specialist's recommendations in the Electronic Medical Record.

5.8.2 Members

5.8.2.1 Formulary Drugs are covered under the prescription drug benefit and are available to members according to their specific plan co-pay or coinsurance (after the deductible is met, if applicable). See the section under *Procedure: A. Formulary Drugs* above for additional clarification.

5.8.2.2 Non-Formulary drugs are not covered under the prescription drug benefit. Members are required to pay full price for non-formulary medications unless the prescribing clinician deems the non-formulary drug to be medically necessary using the exception process *(*see *UM Policy 13a: Formulary Exception Process and Excluded Drug Review).*

5.8.2.3 Tiered cost share plans for brand, generic and specialty products are employed by KPNW. Cost shares for brand, generic and specialty drugs apply as defined by the specific plan.

5.8.2.4 Standard prescription quantities are as defined by the drug benefit: a 30-day supply or unit of use per co-payment or coinsurance (after the deductible is met, if applicable*)* at the clinic level, or a 90 day supply of maintenance medication for two (2) co-payments from the mail order pharmacy as defined by the plan. There are no limits on the number of prescriptions, which may be prescribed per member, or number of refills other than those delineated by state and federal laws or per RFTC recognized therapeutic guidelines established by the FDA.

5.8.3 Pharmacy Staff

5.8.3.1 Each prescription claim is adjudicated through the appropriate Pharmacy Benefit Manager (PBM) system for

accurate benefit application; including any formulary or Utilization Management requirements associated with the insurance plan.

5.8.3.2 Upon receipt, all prescriptions are entered into the computer system and evaluated for correctness by a pharmacist as required by law. The pharmacist verifies the drug, dose, strength, and directions for use and formulary status.

5.8.3.3 If the medication is on the Formulary, the prescription is filled and pharmacy staff collects the appropriate co-pay or coinsurance amount, as appropriate.

5.8.3.4 If the prescription is for a non-Formulary drug, the member may purchase the non-Formulary medication at the retail price. If the patient disagrees with being charged the full retail price, the pharmacist may:

i. Contact the prescribing clinician to suggest using an appropriate Formulary alternative. If the prescribing clinician agrees to convert the non-Formulary medication to the Formulary alternative, the pharmacist makes the change and fills the prescription, charging the member the regular co-payment or co-insurance, as appropriate; or

ii. Member may file grievance/request appeal through Member Relations. If the medication is denied because it was found not to be medically necessary by the prescribing clinician, the medication is dispensed to the member at the retail price. (For additional information on the Exception Process, see *UM Policy 13a: Formulary Exception Process and Excluded Drug Review*).

5.8.4 Generic Substitutions

5.8.4.1 As drugs become available in generic form, they are reviewed by the RFTC based on bioequivalence data provided by the Food and Drug Administration (FDA). Clinicians may deem a non-Formulary branded drug to be medically necessary using the non-Formulary exception review process. If found to be medically necessary, the branded non-Formulary drug is covered at the branded co-pay or co-insurance (after the deductible is met, if applicable) as described in *UM-13a, "Formulary Exception Process and Excluded Drug Review".*

i. Members demanding non-Formulary branded products will pay the retail cost of the drug unless medically necessary as determined through the Criteria-Based Consultation Prescribing review process. (See *UM Policy 13e: Criteria-Based Consultation Prescribing).*
ii. Single-sourced branded formulary drugs are covered under the member's branded co-payment or co-insurance as defined in Section G. 2. d, above.
iii. Pharmacists administer generic substitution as outlined by the state Board of Pharmacy laws.

6.0 Regulatory Requirements

Federal and state regulatory requirements applicable to the P&T formulary management process are monitored on an ongoing basis and reviewed at least annually. The Regulatory Crosswalk Development (RCD) Committee will facilitate monitoring, identifying and updating regulations related to Formulary management.

7.0 References/Appendices

7.1 Oregon State Pharmacy Statutes, Chapter 689. 689.515 Regulation of generic drugs; substitutions; rules: https://oregon.public.law/statutes/ors_689.515

7.2 Washington 69.41.130: Savings in price to be passed on to purchaser: https://app.leg.wa.gov/RCW/default.aspx?cite=69.41.130
Unless the brand name drug is requested by the patient or the patient's representative, the pharmacist shall substitute an equivalent drug product which he or she has in stock if its wholesale price to the pharmacist is less than the wholesale price of the prescribed drug product.

8.0 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: 8/15/2023

Utilization Review Administrator