KAISER PERMANENTE®

Policy Title: Formulary Exception Process and Excluded Drug Review Policy	Policy Number: NW.UM 13A
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
Review Period: 1 Year	Page: 1 of 7

1.0 Policy Statement

A physician or a member may request coverage under the member's pharmacy co-payment or coinsurance (after the deductible is met, if applicable) of a non-formulary drug(s) as medically necessary or of a brand name drug when a generic is the preferred formulary product.

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

2.0 Purpose

To define the standards, accountabilities, and processes for the Clinician exception process for Therapeutic Equivalent drugs (TE) and drugs with generic equivalents on the Formularies.

To provide an objective, evidence-based, consistent review of each individual case in collaboration with a member's clinician. The Regional Formulary and Therapeutics Committee (RFTC) determines what situations require the exception process in accordance with the management of the Formularies and organizational guidelines.

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

4.1 Therapeutic Substitution (TS) Drugs: Therapeutic Substitution (TS) drugs produce essentially the same therapeutic outcome and have similar toxicity profiles. Usually these drugs are within the same pharmacological class or are different dosage forms of the same drug (e.g. tablet instead of a capsule, half-tablet for a full tablet of lesser strength, etc.).

4.2 Generic Equivalents (as defined by the FDA): According to the U.S. Food and Drug Administration (FDA), a generic drug is a copy that is identical to a brand-name drug in dosage, safety, strength, how it is taken, quality, performance and intended use.

5.0 Provisions

5.1 Requests for Coverage
Requests for coverage must meet exception criteria in order to qualify for pharmacy benefit coverage.

5.2 Criteria Review/Revision Timelines:

Criteria will be reviewed/revised by the staff of the Regional Formulary and Therapeutics Committee (RFTC) minimally every 12 months with no greater than 14 months between reviews. Updated criteria will be distributed to Committee members and are available on the Kaiser Permanente Intranet Home page.

5.3 Criteria for Non-Formulary Drug Exception Request:

5.3.1 Exception Criteria

a. Known or predicted failure, intolerance or allergic response to the formulary alternative(s).

b. Short-term approval, when necessary, for new-member transition of care needs.

5.3.2 Other factors of consideration when applying the non-formulary exception criteria may include but are not limited to:

a. Age
b. Progress of treatment
c. Co-morbidity
d. Psychosocial status
e. Home environment when applicable
f. Complications
g. Interacting medications

6.0 Procedures

6.1 NON-FORMULARY EXCEPTION REVIEW PROCEDURE –Initial Reviews

6.1.1 Review Process for New Members: Transition of New Members

a. The New Member Pharmacy Services staff will conduct a phone consultation and/or provide an electronic questionnaire for new members requesting prescription refills within Kaiser Permanente.

b. New Member Pharmacy Services staff will obtain a medication history while helping the member transition their medications into Kaiser Permanente.

c. In consultation with the appointed clinician (or their designee) selected by the new member, the clinical pharmacist will help new members maximize their pharmacy benefit and will forward all data to their appointed clinician for future reference.

d. Members may receive authorization for up to a 30-day supply of medication.

e. If patient does not go through the New Member Pharmacy Services program, then the review process is the same as for existing members in section 6.1.2. below.

6.1.2 Review Process for Existing Members: Clinician Requests. All medications have exception codes. If the clinician applies an exception code at the time of prescribing, the medication is automatically approved without a review by the Formulary Application Services Team (FAST), unless it is an excluded medication or a Criteria-Based Consultation (CBC) medication.

6.1.3 Clinician Review Process for Existing Members: Member Requests to Member Relations

a. Member Relations process will be completed within regulatory timeframes for Commercial, Medicare, and Medicaid business: See Attachment 1.
b. Clinician will review the request using the exception criteria.
c. Documents or systems reviewed may include but are not limited to:
   i. KPNW Health Connect chart notes
   ii. Pharmacy computer-notes
   iii. Information given directly from the patient
   iv. Consultation with prescribing clinician
   v. Consultation with a Clinical Pharmacist
d. Medical necessity approvals may be made by the prescribing clinician.
e. Medical necessity denial determinations are made by the prescribing clinician or a covering physician.
f. Patient and prescribing clinician are notified of review outcome in writing. Denial letters are sent from the Utilization Review Notification Center with appropriate denial reason and appeal information**.** (See *UM Policy 4: Medical Necessity Determinations*.)
g. When a standard exception request is granted, the non-formulary drug must be provided to the member for the duration of the prescription, including refills, unless an addition review is conducted.
   When an expedited exception request is granted, the non-formulary drug must be provided to the member for the duration of the exigency precipitating the expedited request.

On occasion, members will arrive at the pharmacy and verbally request a brand name (non-Formulary) after their clinician had ordered the Formulary drug. When this occurs, pharmacy will discuss alternatives with the patient. For those issues that cannot be resolved, pharmacy will send a telephone encounter to the clinician instructing them to either 1) state the brand is not medically necessary and instruct the member to either pay for the brand or contact Membership Services to start the appeal process or 2) call FAST and initiate a brand review request.

6.2 Exception Review process for Appeals - Department Specific Procedural Information.

6.2.1 After an appeal is received, Member Relations will submit the appropriate documentation to a Utilization Management Physician.

6.2.2 The Utilization Management Physician will make a coverage decision based on a member chart review, in conjunction with prescribing clinician as needed, and then notifies Member Relations of the decision. Member Relations will communicate the decision to the member. Member Relations will also notify FAST as an FYI to help facilitate the necessary exception code or override.

6.2.3 Utilization Management Physician decisions shall include a specific denial or approval reason (i.e. what criteria the member does meet for approval or what criteria the member does not meet for a denial).

6.2.4 Appeal decision and notification turnaround times are defined in UR 26 Appeals of Adverse Determinations Policy.

The following EXCEPTIONS apply to On Exchange/Marketplace formulary exception requests:
Decisions and notifications are turned around in the following timeframes: 72 hours for pre-service routine appeals and 24 hours for pre-service expedited appeals.
Members are offered a simultaneous internal and external appeal process for expedited formulary exception requests.

6.3 EXCLUDED DRUG REVIEW PROCEDURE

6.3.1 If a drug whose primary indication is excluded from coverage is prescribed for another indication which is not excluded from coverage, that drug may be reviewed for a Pharmacy benefit exception on a patient specific basis. Review process will be completed within two business days of the clinician's request.

a. The following criteria should be considered for such reviews:

i. Request for coverage is from a Clinician.

ii. Specialty provider is consulted and approves of treatment plan.
iii. There is documented evidence in the scientific literature that the drug is effective and safe for prescribed indication.
iv. Member has history of treatment failure with, or is inappropriate candidate for, formulary alternatives.
v. RFTC staff must be contacted prior to initiating therapy.

b. The following process should occur when a request of this nature is considered:
   i. Clinician contacts RFTC staff, discusses specific case and previous therapies with Clinical Pharmacist.
   ii. Clinical Pharmacist:
      - Performs a review of scientific literature to evaluate safety and efficacy of proposed drug therapy
      - Performs review of patient medical record
      - Determines that formulary therapies will not achieve therapeutic goal
      - Consults with clinician specialist
      - Discusses case with RFTC Chair
   iii. If approved, the Pharmacist will contact the prescribing clinician to establish guidelines for use and process for ordering the medication to facilitate smooth access and coverage of the drug therapy throughout the system.

6.3.2 Drugs used for indications excluded from coverage by contract language are not eligible for a Pharmacy benefit exception review.

7.0 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: 8/15/23

Utilization Review Administrator

Appendix A

Attachment 1: **NW TURN-AROUND TIMES INITIAL DETERMINATION/ NOTIFICATION/ EXTENSION**

<table>
<tr><th></th><th>Oregon Commercial</th><th>Washington Commercial</th><th>Oregon Medicaid (HealthShare)</th><th>Washington Medicaid (Molina)</th><th>Medicare Part D</th></tr>
<tr><td>Pre-service Routine</td><td>Decision and notification within two business days from receipt of request</td><td>Decision and notification within five calendar days from receipt of necessary information</td><td rowspan="2">Respond to prior authorizations within 24 hours.

May request additional information when documentation lacks sufficient info to render decision. If additional info not received within 72 hours, prior auth can be denied.

If a substantiated medical emergency or immediate medical need, 72 hour supply shall be made until final decision is made.</td><td rowspan="2">Decision and notification within 24 hours from receipt of request, unless additional information is needed. Any additional info needed must be requested by close of business on the first day following the initial request, and decision must be made no later than close of business on the first business day after receipt of the additional information.</td><td rowspan="2">Decision and notification within 72 hours</td></tr>
<tr><td colspan="2">EXCEPTION:
On-Exchange/ Marketplace-
Decision and notification within 72 hours from receipt of request</td></tr>
<tr><td>Pre-service Urgent / Expedited</td><td>Decision and verbal notification within two business days, not to exceed 72 hours, unless sufficient information is not provided by claimant.

Additional three calendar days allowed to issue written notification.</td><td>Decision and verbal notification within 48 hours, unless sufficient information is not provided by claimant.

Additional three calendar days allowed to issue written notification.</td><td rowspan="2">Decision and written notification - Expeditiously; no more than 72 hours</td><td rowspan="2">Decision and verbal or fax notification within one business day of request. Written denial notification to member and provider within three calendar days of verbal notification of denial.</td><td rowspan="2">Decision and notification within 24 hours</td></tr>
<tr><td colspan="2">EXCEPTION:
On-Exchange/ Marketplace-
Decision and notification within 24 hours from receipt of request</td></tr>
</table>

Urgent Concurrent	Urgent: Decision and Verbal Notification- **24 hours** from receipt of request. Additional three calendar days allowed for written notification. Non-urgent: follow "Pre-service Routine" timelines	Urgent: Decision and Verbal Notification- **24 hours** from receipt of request. Additional three calendar days allowed for written notification. Non-urgent: follow "Pre-service Routine" timelines	Urgent: Decision and Verbal Notification- **24 hours** from receipt of request. Additional 72 hours allowed for written notification. Non-urgent: Decision and written notification ten calendar days prior to termination, suspension or reduction of previously authorized covered service	Urgent: Decision and Verbal Notification- **24 hours** from receipt of request. Additional 72 hours allowed for written notification. Non-urgent: Decision within one business day of receipt of request; extend three business days if one attempt to obtain needed information. Notification within one business day after decision.	Urgent: Decision and notification within 24 hours Non-urgent: Decision and notification within 72 hours
Retrospective / Post-service	Decision and notification within 30 calendar days	Decision and notification within 30 calendar days	Decision and Notification- 30 calendar days from receipt of necessary information	Decision and Notification- 30 calendar days from receipt of necessary information	Decision and notification within 14 calendar days from receipt of necessary information