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 formulary.

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 formulary and organizational guidelines.

Examples include, but are not limited to:

1. **A physician or member requests 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.**

2. **A physician or member requests coverage under the member’s pharmacy co-payment or coinsurance (after the deductible is met, if applicable) of a brand name drug when a generic is the preferred formulary product.**

DEFINITIONS

A. **Therapeutic Equivalent (TE) Drugs:** Therapeutic Equivalent drugs (TE) 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.).

B. **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.

POLICY

A. **Requests For Coverage**

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

B. **Criteria review/revision timelines:**

   1. 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.
C. Criteria for Non-Formulary Drug Exception Request:

1. Exception Criteria
   a. Documented/substantiated intolerance to the Formulary alternative(s).
   b. Documented/substantiated allergy to the formulary alternative(s).
   c. Documented/substantiated treatment failure with the formulary alternative.

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

NON-FORMULARY EXCEPTION REVIEW PROCEDURE –Initial Reviews

A. Review Process for new members: Transition of New members

1. The New Member Pharmacy Services staff will conduct a phone consultation for new members requesting prescription refills within Kaiser Permanente.

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

3. In consultation with the appointed clinician or designee (DOD or Doctor of the Day) 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.

4. Members may receive authorization for up to a 90 day supply of medication to last until their scheduled appointment, which in most cases is 30 days.

B. Review process for existing members: Clinician Requests. All medications have exception codes (except excluded medications and Criteria Based Consultation (CBC) medications which is addressed in another policy). If the clinician applies an exception code at time of prescribing, FAST does not do any review of the medications.

C. Clinician Review process for existing members: Member Requests
1. Member Relations process will be completed within regulatory timeframes for Commercial; Medicare; and Medicaid business: See Attachment 1.

2. Clinician will review the request using the exception criteria.

3. Documents or systems reviewed may include but are not limited to
   a. KPNW Health Connect chart notes
   b. Pharmacy computer (TOPS) notes
   c. Information given directly from the patient
   d. Consultation with prescribing clinician
   e. Consultation with Drug Information Therapeutic Expert Pharmacist

4. Medical necessity approvals may be made by the prescribing clinician.

5. Medical necessity denial determinations are made by the prescribing clinician or a covering physician.

6. Patient is notified of review outcome in writing.
   a. Denial letters are sent from Member Relations with appropriate appeal information. (See UM-4, Medical Necessity Determinations.)

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, patient is directed to Membership Services (to start the review process with Member Relations) if the issue could not be resolved by pharmacy contacting clinician for an alternate medication or convincing patient to try an alternative medication.

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

A. After FAST is notified by Member Relations of appeal receipt, FAST will submit appeal and applicable documentation to RFTC physician, if the member states s/he does meet the exception criteria.

B. RFTC Physician makes a coverage decision based on member chart review, in conjunction with prescribing clinician as needed, and then, notifies FAST of decision.

C. RFTC 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).

**EXCLUDED DRUG REVIEW PROCEDURE**
A. 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.

1. The following criteria should be considered for such reviews:
   a. Request for coverage is from a Clinician.
   b. Specialty provider is consulted and approves of treatment plan.
   c. There is documented evidence in the scientific literature that the drug is effective and safe for prescribed indication.
   d. Member has history of treatment failure with, or is inappropriate candidate for, formulary alternatives.
   e. RFTC staff must be contacted prior to initiating therapy.

2. The following process should occur when a request of this nature is considered:
   a. Clinician contacts RFTC staff, discusses specific case and previous therapies with Drug Information Pharmacist.
   b. Drug Information Pharmacist:
      i. Performs a review of scientific literature to evaluate safety and efficacy of proposed drug therapy
      ii. Performs review of patient medical record
      iii. Determines that formulary therapies will not achieve therapeutic goal
      iv. Consults with clinician specialist
      v. Discusses case with RFTC Chair
   c. 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.

B. Drugs used for indications excluded from coverage by contract language are not eligible for a Pharmacy benefit exception review.
## Title: Formulary Exception Process and Excluded Drug Review

**Department:** Pharmacy Services  
**Applies to:** KPNW Region.  
**Review Responsibility:** RFTC  
**SME:** Emily Thomas, PharmD  
**Number:** UR 13a  
**Issued:** 7/96  
**Reviewed by RFTC:** 4/01, 6/01, 6/02, 8/04, 10/04, 12/05, 4/06, 10/07, 4/09, 6/10, 7/11, 6/12  
**Reviewed by UMPS/RUMC/UROC:** 2/03, 1/04, 11/04, 12/05, 6/06, 8/07, 11/07, 11/08, 5/09, 7/10, 7/11, 7/12  
**Revised:** 7/12

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

<table>
<thead>
<tr>
<th>OR CO (incl. OEBB)</th>
<th>OR Medicaid</th>
<th>WA CO (incl. PEBB)</th>
<th>WA Medicaid</th>
<th>Medicare</th>
<th>ERISA</th>
<th>NCQA</th>
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</thead>
<tbody>
<tr>
<td><strong>Pre-service Routine</strong> (provider requests)</td>
<td>Decision and Notification- 2 BD from receipt of request</td>
<td>Decision and Notification- 5 CD from receipt of necessary information</td>
<td>Decision and Notification- 14 CD from receipt of request</td>
<td>Decision and Notification- 14 CD from receipt of request; may extend 14 CD to obtain necessary information</td>
<td>Decision and Notification- 15 CD from receipt of request; may extend 15 CD if due to matters beyond the organization's control and the patient is notified before the 15 CD have expired</td>
<td>Decision and Notification- 15 CD from receipt of request; may extend 45 CD to obtain necessary information</td>
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<td><strong>Pre-service Urgent/ Expedited</strong> (Per NCQA, not to exceed 72 H)</td>
<td>Decision and Notification- 2 BD from receipt of request- includes alcohol and drug services &amp; care required while in a SNF; may extend 14 CD</td>
<td>Decision and Notification- 48 H from receipt of necessary information</td>
<td>Decision and Notification- 14 CD from receipt of request</td>
<td>Decision and Notification- 72 H from receipt of request</td>
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<td>Decision and Notification- 72 H from receipt of request</td>
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<tr>
<td><strong>Concurrent</strong></td>
<td>Decision and Notification- 10 CD prior to termination of previously authorized service (additional 3 CD for written notification)</td>
<td>Decision and Notification- 24H from receipt of request (additional 24H for written notification)</td>
<td>Decision and Notification- 10 CD prior to termination of previously authorized service (additional 3 CD for written notification)</td>
<td>Decision and Verbal Notification- 24H from receipt of request (additional 3 CD for written notification)</td>
<td>Decision and Verbal Notification- 24H from receipt of request (additional 3 CD for written notification)</td>
<td>When urgent, Decision and Verbal Notification- 24H from receipt of request (additional 3 CD for written notification)</td>
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**BD= business days**  
**CD= calendar days**  
**H= hours**  
**OR  CO** (incl. OEBB)  
**OR Medicaid**  
**WA CO** (incl. PEBB)  
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## Title: Formulary Exception Process and Excluded Drug Review

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<td><strong>Post-Service</strong></td>
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<tr>
<td>Decision and Notification-30 CD from receipt of necessary information</td>
<td>Decision and Notification-30 CD from receipt of necessary information</td>
<td>Decision and Notification-30 CD from receipt of necessary information</td>
<td>Decision and Notification-14 CD from receipt of necessary information</td>
<td>Decision and Notification-30 CD from receipt of necessary information</td>
<td>Decision and Notification-30 CD from receipt of necessary information; may extend up to 50 CD if member is notified within 30 CD of receipt of request.</td>
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<tr>
<td><strong>Member Requests (pre-service routine)</strong></td>
<td><strong>NON-ERISA ONLY:</strong></td>
<td>Decision and Notification-14 CD from receipt of request</td>
<td>Decision and Notification-5 CD from receipt of necessary information</td>
<td>Decision and Notification-14 CD from receipt Part D: Decision and Notification – 72 H from receipt If request is for an exception without supporting documentation, may extend to total of 96H to obtain needed information.</td>
<td>Decision and Notification-15 CD from receipt of necessary information</td>
<td>Decision and Notification-15 CD from receipt of necessary information; may extend 45 CD to obtain necessary information</td>
</tr>
</tbody>
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