

<b>Policy Title: Criteria-Based Consultation Prescribing/Step Therapy</b>	<b>Policy Number: NW.UM 13E</b>
<b>Owner Department: Pharmacy</b>	<b>Effective Date: 03/2004</b>
<b>Custodian: Emily Thomas, PharmD</b>	<b>Last Review / Revision Date: 07/2023</b>
<b>Approver: Utilization Review Oversight Comm.</b>	<b>Next Review Date: 07/2024</b>
<b>Review Period: 1 Year</b>	<b>Page: 1 of 4</b>

## 1.0 Policy Statement

Criteria-based consultation (CBC) drugs are drugs for which therapeutic alternatives or approved generic equivalent(s) are available, drugs that should only be used for specific health conditions, or drugs that are only to be prescribed by providers with the appropriate expertise. For a CBC drug to be authorized for coverage on the prescription drug benefit, its use must meet defined criteria. The ordering clinician is responsible for ordering the prescription and completing the CBC drug's criteria questions justifying its use.

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

## 2.0 Purpose

The Kaiser Permanente Northwest Regional Formulary and Therapeutics Committee (RFTC) has developed prescribing criteria to apply to selected medications. Medications classified as criteria-based or step therapy are usually second- or third-line medications for the treatment of a specific disease state. The RFTC uses both internal and external resources, including Specialty Department input, Food and Drug Administration recommendations, and clinical trials published in the medical literature to guide them in the creation of prescribing criteria. This process is a cornerstone of the KPNW Formulary Process.

## 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** Step Therapy: RFTC may recommend that certain drugs be chosen as second- or third-line medications in the treatment of specific disease states. If the first- or second-line agents are ineffective or not tolerated, clinicians may prescribe drugs that are designated as step therapy. First- and second-line agents are selected after careful review of medical literature, manufacturer product information, and consultation with formulary consultants and department chiefs. A clinician may also request an exception to step therapy if he or she determines that the first- and second-line medication options are not appropriate for a specific patient.

**4.2** Second-line or third-line medications: Treatment that is given when initial (first-line therapy) or subsequent (second-line therapy) treatment is contraindicated, not tolerated (including allergy), or not effective.

**4.3** Criteria Based Consultation (CBC) medications: drugs that have specific criteria for use.

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## 5.0 Provisions

### 5.1 Criteria

#### 5.1.1 Development:

- a. Prescribing criteria are established for specific drugs by the RFTC.
- b. A pharmacist reviews the available information, including the prescribing information, independent studies, and other recognized authoritative compendia and creates criteria for review with assistance of Specialty Departments. The physician specialist provides input regarding the appropriate use of a specific drug.
- c. RFTC approves the final criteria.
- d. Criteria are reviewed at least annually or when changes are made.
- e. Previous criteria are archived indefinitely (a minimum of 10 years).

#### 5.1.2 Clinicians requesting a CBC drug will evaluate and document as required:

- a. Use of one or more alternatives.
- b. Contraindication, treatment failure, intolerance, or allergy to one or more alternatives.
- c. Diagnosis of any approved indication.
- d. Specialist consult or recommendation.
- e. Laboratory monitoring.
- f. Age appropriateness.
- g. Lab values.
- h. Prescribing program enrollment for clinicians or members.
- i. Any other criteria required to support evidence-based use.

#### 5.1.3 Criteria are posted publicly on kp.org and are also available upon request to members or clinicians.

### 5.2 Criteria Based Consultation Drugs

- 5.2.1 Criteria Based Consultation drugs are covered under the benefit and available for the member's applicable cost share when medically necessary and the member meets the established criteria.
- 5.2.2 No incentives are employed to influence prescribing decisions by clinicians who select Criteria Based Consultation drugs.
- 5.2.3 Use of Criteria Based Consultation drugs may be restricted to one or more specialty groups. This restriction may be due to:

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- a. Potential for significant safety concerns.
  - b. High potential for adverse effects.
  - c. High cost-to-benefit ratio in conjunction with other clinical concerns.
  - d. High potential for abuse.
- 5.2.4 For additional information, see the [Criteria Based Consultation Prescribing Website](#), which includes a listing of criteria-based drugs.

## **6.0 Procedures for CBC Drugs**

- 6.1** The ordering clinician will determine appropriate medication therapy based on current regional treatment guidelines, the member’s known drug history, and documented diagnosis.
- 6.2** If a criteria-based medication is selected, the completed form is transmitted electronically to and processed by the Formulary Application Services Team (FAST).
- 6.2.1 A pharmacist will review the patient’s chart to determine if criteria are met.
  - 6.2.2 If criteria are not met and time allows, a note will be sent to the prescriber, and he or she is given the opportunity to update to a preferred alternative. If a preferred alternative is not ordered, the request is forwarded to a reviewing physician for determination of approval or denial.
  - 6.2.3 Member is notified of approval or denial in writing within regulatory guidelines (see UR 4 Utilization Management Medical Necessity Determinations Policy and UR 26 Appeals of Adverse Determination Policy). The Utilization Review Notification Center will issue a formal denial letter if medication is denied.
- 6.3** When all criteria are met, the drug will be covered at the member’s pharmacy co-pay or coinsurance (after the deductible is met, if applicable). When criteria are not met, the drug will not be covered by the member’s pharmacy benefit.
- 6.3.1** The Utilization Review Notification Center will generate a denial letter with appropriate appeal information (see UR 4 Utilization Management Medical Necessity Determinations Policy).
  - 6.3.2** At any time, a member may choose to purchase a Criteria Based Consultation drug that has been deemed not medically necessary by paying full price for the drug.

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6.4 For the member appeal process, refer to UR 26 Appeals of Adverse Determination Policy.

### **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 8/15/2023

Utilization Review Administrator