

POLICY TITLE <b>Medicare Part B Step Therapy</b>	POLICY NUMBER <b>WA.PHARM.BEN.008</b>
ACCOUNTABLE DEPARTMENT <b>Pharmacy, KPWA</b>	EFFECTIVE DATE <b>07/26/2024</b>
DOCUMENT OWNER <b>Regional Administrator, Pharmacy</b>	PAGE <b>1 of 3</b>
APPROVAL BODY/COMMITTEE <b>KPWA, Pharmacy Policy and Procedures Committee</b>	DATE APPROVED <b>07/26/2024</b>

## 1.0 Policy Statement

In 2018, the Centers for Medicare and Medicaid Services (CMS) updated its guidance to allow Medicare Advantage (MA) plans the option to implement step therapy for Part B drugs to lower drug prices while maintaining access to covered services and drugs for beneficiaries.

Effective January 1, 2021, Kaiser Foundation Health Plan of Washington (KFHPWA) MA plans implement step therapy to a selected non-preferred Part B drugs to promote clinically appropriate and cost-effective drug options for members. A list of these drugs and the associated step therapy requirement is posted on the KFHPWA website [www.kp.org/wa/medicare](http://www.kp.org/wa/medicare).

This policy applies to a selected list of Part B drugs reviewed and approved by the regional P&T Committee only. Certain diagnoses may be excluded from the step therapy requirement.

## 2.0 Purpose

This policy supplements Medicare National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), and manuals for the purpose of determining coverage under Medicare Part B medical benefits.

## 3.0 Scope/Coverage

This policy applies to all individuals who are employed by the following entities (collectively referred to as "Kaiser Permanente"):

- 3.1** Kaiser Foundation Health Plan, Inc. (KFHP);
- 3.2** All contractors, vendors, volunteers, students, or other persons, who are KP workforce members, while performing functions or services for or on behalf of KFHP, KFHP and/or the PMGs (individually, a "KP entity").

## 4.0 Definitions

- 4.1 Centers for Medicare & Medicaid Services (CMS)** – The Health and Human Services (HHS) agency responsible for Medicare and Medicaid.
- 4.2 Member(s)** – Individuals and their dependents that are identified by the organization as entitled to access and obtain health care services, subject to eligibility requirements and benefit limitations as defined by the organization.

## 5.0 Provisions

### 5.1 Applicability

- 5.1.1** This policy and procedure support the requirements stated in this document and is approved for Kaiser Foundation Health Plan of Washington (KFHPWA) Medicare Advantage plan.

### 5.2 Medicare Advantage Compliance

- 5.2.1** All KFHPWA Medicare Advantage policies and procedures are reviewed and approved annually per the KFHPWA Medicare Advantage Compliance Program requirements.

POLICY TITLE <b>Medicare Part B Step Therapy</b>	POLICY NUMBER <b>WA.PHARM.BEN.008</b>
ACCOUNTABLE DEPARTMENT <b>Pharmacy, KPWA</b>	EFFECTIVE DATE <b>07/26/2024</b>
DOCUMENT OWNER <b>Regional Administrator, Pharmacy</b>	PAGE <b>2 of 3</b>
APPROVAL BODY/COMMITTEE <b>KPWA, Pharmacy Policy and Procedures Committee</b>	DATE APPROVED <b>07/26/2024</b>

### 5.3 Step Therapy Components

**5.3.1** Step therapy requirements will apply to **new starts only**. A member cannot be required under this policy to change a current drug. The current drug means the member has a paid claim for the drug within the past 365 days.

5.3.1.1 For example, a new plan member currently using a particular drug will not be required to switch to the preferred drug upon enrollment.

5.3.1.2 Similarly, an existing member currently using a particular drug will not be required to change drugs.

**5.3.2** Members/providers may request exceptions to step therapy.

5.3.2.1 Exceptions are approved where the provider’s supporting statement shows an exception is medically necessary.

### 5.4 Review Timeframes

**5.4.1** The Help Desk reviews and notifies the member within the CMS required timeframe for review as per the below:

<b>EXPEDITED</b> requests	No later than <b>24 hours</b> from receipt of the prescriber’s supporting statement
<b>STANDARD</b> requests	No later than <b>72 hours</b> from receipt of the prescriber’s supporting statement

### 5.5 Reporting Requirements

**5.5.1** KFHPWA MA plans report data related to the Part B Step Therapy when requested by CMS.

### 5.6 Records Retention

**5.6.1** KFHPWA MA plans comply with the CMS requirement for records retention for the current contract period and 10 prior contract periods to ensure the availability to CMS, Department of Health and Human Services (DHHS), the Comptroller General, or their designee, access to Medicare Advantage Organization facilities and records to evaluate through inspection or other means.

### 5.7 Internal Audit Process

**5.7.1** KFHPWA MA plans comply with the CMS requirement for conducting internal audits and reporting internal audit results and findings as required by CMS.

**5.7.2** All KFHPWA operational areas with responsibility for ensuring compliance with CMS requirements must complete internal audits as directed by the Director of Medicare Programs and Compliance.

POLICY TITLE <b>Medicare Part B Step Therapy</b>	POLICY NUMBER <b>WA.PHARM.BEN.008</b>
ACCOUNTABLE DEPARTMENT <b>Pharmacy, KPWA</b>	EFFECTIVE DATE <b>07/26/2024</b>
DOCUMENT OWNER <b>Regional Administrator, Pharmacy</b>	PAGE <b>3 of 3</b>
APPROVAL BODY/COMMITTEE <b>KPWA, Pharmacy Policy and Procedures Committee</b>	DATE APPROVED <b>07/26/2024</b>

**5.7.3** Medicare Programs and Compliance and the Kaiser Permanente National Compliance Office (NCO) reports internal audit results to CMS Regional office as required.

**5.8 Corrective Action**

**5.8.1** Corrective actions are self-identified by operational departments or identified by Medicare Programs and Compliance and are implemented by operational areas.

**5.8.2** Correction Action Plan (CAP) implementation is initiated with oversight by Medicare Programs and Compliance.

**5.8.3** Operational area reporting frequency is weekly or monthly to Medicare Programs and Compliance and NCO reports to CMS as required.

**5.8.4** Medicare Programs and Compliance reports to CMS as required.

**6.0 Appendices/References**

**6.1 Other References**

**6.1.1** [HPMS Memos Dated 08/07/2018](#)

**6.1.2** [CMS Final Rule Dated 05/23/2019](#)

**6.2 Appendices**

**6.2.1** N/A