

Department of Origin: Pharmacy	Date approved: 1/19/2023
Approved by: Chief Medical Officer	Effective Date: 1/23/2023
Pharmacy Clinical Policy Document: Step Therapy	Replaces Effective Policy Dated: 2/4/2022
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PURPOSE:

The intent of this pharmacy clinical policy is to provide coverage guidelines for step therapy.

Step therapy is a method employed by pharmacy benefit managers (PBM) and health plans to provide a high-quality and cost-effective prescription drug benefit. It promotes the use of clinically appropriate prescription drug options while respecting the provider's prescribing authority.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Where indicated, members may be required to follow a *step therapy protocol* for specified medical conditions.

Approval of a drug under a *step therapy protocol* does not ensure full coverage of the drug. Other pharmacy programs may be in place affecting supply and payment of the medication, such as but not limited to prior authorization, formulary exceptions (see Pharmacy Clinical Policy: PC/F002 Formulary Exceptions) and quantity limits (see Pharmacy Clinical Policy: PP/Q003 Quantity Limits). Please check the members' prescription drug benefits for details of other pharmacy programs.

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

COVERAGE:

- I. When a *step therapy protocol* is in place for a self-administered medication and the first line or predicate alternative(s) has/have not been trialed, a reject message is sent to the pharmacy.
- II. The number of first line or predicate medication(s) that are required to be tried before allowing an alternative medication will vary for different drug classes depending on the availability of first line medications and the specific goals of the *step therapy protocol* for that drug class.
- III. Clinical review for a *step therapy override* is necessary when the prescribing provider feels the first line or predicate medication(s) is not appropriate (such as, but not limited to, when the member has not responded to, is intolerant to, or a poor candidate for a first line or predicate medication(s)).
- IV. A *step therapy override* is granted when clinical documentation supports one or more of the following: A-E
 - A. The prescription medication required under the *step therapy protocol* is contraindicated for the member, based on the pharmaceutical manufacturer's prescribing information for the drug; or
 - B. The member has a history of an adverse reaction with previous use of the medication; or
 - C. The member has a medical condition, including a comorbid condition, that is likely to do any of the following:
 1. Cause an adverse reaction; or

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2. Decrease the ability of the member to achieve or maintain a reasonable functional ability in performing *activities of daily living* (ADLs); or

3. Cause physical or mental harm.

D. The member has completed a trial of the required prescription medication (eg, first line/predicate medication[s]) covered by their current or previous health plan, or another prescription medication in the same pharmacologic class or with the same mechanism of action and both of the following occurred: 1 - 2

1. Was adherent during such trial for a period of time sufficient to allow for a positive treatment outcome; and

2. The medication was discontinued by a provider due to lack of effectiveness or an adverse event.

[Note: A member may be required to try another medication in the same pharmacologic class or with the same mechanism of action if that therapy sequence is supported by *reliable evidence*.]

E. The member is currently receiving a positive therapeutic outcome on a medication for the medical condition under consideration (whether under the current health plan or the immediately preceding health plan) and the prescribing provider submits documentation that the change in prescription medication required by the *step therapy protocol* is expected to be ineffective or cause harm to the member.

V. Use of co-pay assistance outside of the prescription drug benefit or use of samples will count as treatment when determining if a *step therapy protocol* has been met for medications where interchange may cause a health risk (i.e. antiarrhythmics, anticoagulants, anticonvulsants, antidepressants, antineoplastics, and antipsychotics/psychotropics, antiretrovirals and immunosuppressants [when used for prophylaxis of organ transplant rejection]). For all other medications, the use of co-pay assistance or samples will not meet *step therapy protocol* requirements.

VI. PIC and PAS Non-ERISA plans - A *step therapy protocol* will not be applied when both of the following are present: A - B

A. The member has *stage four advanced metastatic cancer* or associated conditions: and

B. The request for the approved medication is consistent with any of the following: 1 - 2

1. An FDA approved indication; or

2. A clinical practice guideline published by the National Comprehensive Cancer (Care[sic]) Network.

PROCEDURE:

Initiation of a *step therapy override* request (see step therapy programs on the PreferredOne website: www.preferredone.com under the Pharmacy section):

I. The drugs that are affected by *step therapy protocols* are dependent on the prescription drug benefit and PBM. Members and providers may determine what drugs and/or drug classes fall into *step therapy protocols* by:

A. Calling the Customer Service telephone number listed on the member's insurance card; or

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- B. Accessing PreferredOne.com or the applicable PBM's website.
- II. The member's prescribing provider must submit a written request for a *step therapy override* on behalf of the member with clinical information supporting the request. This can be initiated by:
- A. Calling the Customer Service telephone number listed on the member's insurance card; or
- B. Completing the Medication Request Form which can be found at <https://www.preferredone.com/providers/pharmacy-resources.aspx>;
- III. Information submitted by the provider must be complete and appropriate to the request submitted. Incomplete forms will be returned to the requestor.
- IV. Requests for *step therapy override* will be reviewed on a case-by-case basis.
- V. Timeframes for completion and notification of a step therapy override request or appeal
- A. An urgent concurrent request will be completed within 24 hours of receipt of complete information.
- B. An urgent preservice request will be completed within 48 hours (and must include at least one business day) of receipt of complete information.
- C. A non-urgent preservice request will be completed within 5 business days of receipt of complete information.
- D. Postservice decisions are made within 30 calendar days of receipt of complete information.
- VI. Notification method and process after completion of a *step therapy override* request or appeal
- A. If a *step therapy override* request is approved:
1. PreferredOne will enter an override in the PBM processing system to allow adjudication of the prescription.
 2. PreferredOne will notify the provider and member by electronic or written notification.
 3. For PIC and PAS Non-ERISA members, PreferredOne will also the provider telephonically or by facsimile.
- B. If a *step therapy override* request is not approved:
1. PreferredOne will notify the provider of the denial and appeal rights by electronic or written notification.
 2. PreferredOne will notify the member of the denial and appeal rights by written notification.
 3. For PIC and PAS Non-ERISA members, the attending provider (and hospital, as applicable) will be notified by telephone, facsimile to a verified number or by electronic mail to a secure electronic mailbox.

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EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description.

DEFINITIONS:Activities of Daily Living (ADL):

Activities related to personal self-care and independent living, which include eating, bathing, dressing, transferring, walking/mobility, and toileting/continence.

Authoritative Compendia:

American Hospital Formulary Service- Drug Information (AHFS-DI), National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium, Micromedex DrugDex, Clinical Pharmacology, and Lexi-Drugs

Reliable evidence:

PreferredOne will consider the following categories of reliable evidence, none of which shall be determinative by itself:

1. Whether there is a final approval from the appropriate government regulatory agency, if required. This includes whether a drug or device can be lawfully marketed for its proposed use by the FDA; or if the drug, device or medical treatment or procedure is under study or if further studies are needed to determine its maximum tolerated dose, toxicity, safety or efficacy as compared to standard means of treatment or diagnosis; and
2. Whether there are consensus opinions or recommendations in relevant scientific and medical literature, peer-reviewed journals, or reports of clinical trial committees and other technology assessment bodies. This includes consideration of whether an oncology treatment is included in the applicable National Comprehensive Cancer Network (NCCN) guideline, as appropriate for its proposed use, or whether a drug is included in any authoritative compendia as identified by the Medicare program such as, the National Comprehensive Cancer Network Drugs and Biologics Compendium, as appropriate for its proposed use; and
3. Whether there are consensus opinions of national and local health care providers in the applicable specialty as determined by a sampling of providers, including whether there are protocols used by the treating facility or another facility, studying the same drug, device, medical treatment or procedure.

Stage four advanced metastatic cancer:⁹

Cancer that has spread from the primary or original site of the cancer to nearby tissues, lymph nodes or other parts of the body.

Standard Reference Compendia:

Authoritative compendia as identified by the Medicare program for use in the determination of a medically accepted indication of drugs and biologics used off-label.

Step Therapy Protocol:

A protocol or program that establishes the specific sequence in which prescription drugs for a specified medical condition, including self-administered and physician-administered drugs, are medically appropriate for a particular member and are covered under the health plan.

Step Therapy Override:

When a step therapy protocol is overridden in favor of coverage of the selected prescription drug of the prescribing/ordering provider.

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REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Clinical Policy: MP/L004 Levels of Evidence and the Evaluation of Health Care Services
4. Pharmacy Clinical Policy: PC/F002 Formulary Exceptions
5. Pharmacy Clinical Policy: PP/Q003 Quantity Limits
6. Pharmacy Clinical Policy: PP/O001 Off-Label Drug Use
7. Minnesota Statute 62M.05 Procedures for Review Determination
8. Minnesota Statute 62Q.184 Step Therapy Override
9. Minnesota Statute 62Q.1841 Prohibition on use of Step Therapy for Metastatic Cancer
10. Medicare Benefit Policy Manual. Chapter 15, 50.4.5 – Covered Medical and Other Health Services. Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen. (Rev. 10880, Issued: 08-06-21, Effective: 08-06-21, Implementation: 11-08-21). Retrieved from <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>. Accessed 01-18-23.
11. NCQA 2021 HP Standards and Guidelines
 - UM 5: Timeliness of UM Decisions
 - UM 11: Procedures for Pharmaceutical Management

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PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:

Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

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ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອຕໍ່ພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013) .

ဟ်သ့ဟ်သး- နမံကတိ၊ ကညိ ကျိာ်အယံ၊ နမံကျိာ်အတိမၤစၢလၢ တလၢာ်ဘျဉ်လၢာ်စၢ နီတမံဘျဉ်သန့လီၤ. ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

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PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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