PreferredOne®

Department of Origin: Pharmacy	**Date Approved:** 1/19/2023
Approved by: Chief Medical Officer	**Effective Date:** 1/23/2023
Pharmacy Clinical Policy Document: Formulary Development, Structure, and Management	**Replaces Effective Policy Dated:** 03/08/2022
Reference #: PP/F002	**Page:** 1 of 4

PURPOSE:
The intent of this policy is to describe the development, structure and management of the PreferredOne *formularies*. PIC formularies are developed and managed by the PreferredOne Pharmacy & Therapeutics (P&T) Quality Management (QM) Subcommittee. The development and management of the PAS formularies are not managed by the PreferredOne P&T QM Subcommittee.

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:
The PreferredOne P&T QM Subcommittee develops and approves evidence-based *formularies* for PIC that includes medications, products, and therapies that are medically appropriate and cost-effective. The *formularies* meet applicable federal and state regulations and mandates, including state of Minnesota benchmarks for Essential Health Benefits (EHB), where required. The *formularies* and medication classes are reviewed and approved on at least an annual basis.

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. *Formulary* Categories and Classes

A. PreferredOne *formularies* utilize a nationally recognized medication classification system (eg, MediSpan or First Databank) to designate medications by therapeutic class.

B. PreferredOne ensures each therapeutic category and class on the *formularies* include coverage as follows:
   1. At least one covered and chemically distinct medication.

   2. Other medications may be added to create covered or preferred tier levels.

C. PreferredOne may exclude specific categories and/or classes from coverage due to benefit exclusions and/or lack of regulatory requirement(s) mandating coverage under state EHB standards.

II. *Formulary* Structure

A. PreferredOne *formularies* provide clinically appropriate access to medications that cover all disease states addressed in widely accepted national treatment guidelines and are indicative of general best practices.

B. PreferredOne *formularies* utilize benefit management tools including prior authorization, step therapy, quantity limitations, biosimilar and generic substitution that are consistent with best practices and federal and state regulations and mandates.

III. *Formulary* Management – Open and Closed

A. The P&T QM Subcommittee meets quarterly. Additional P&T QM Subcommittee meeting(s) may occur on an ad-hoc basis, to determine formulary status of a newly approved medication or product.

B. The P&T QM Subcommittee makes a reasonable effort to review a new FDA approved medication or product within 90 days of its market availability and will finalize a decision on each new medication or product within 180 days.

C. PreferredOne may make a *formulary enhancement* at any time during the year, such as, but not limited to, addition of newly approved medications, including brand, generic, specialty medications and *biologic* or *biosimilar* products.
   1. A medication or product may be added to a formulary at any time as a *formulary enhancement*.

   2. When the *formulary enhancement* results in a medication or product that is *interchangeable* and/or therapeutically equivalent to an existing formulary medication or product and is a lower net cost, either of the following may occur: a or b
      a. An existing formulary medication or product may be moved to a different cost tier; or
      b. An existing formulary medication or product may be excluded from coverage under the Cost Benefit program

D. Consistent with state and federal laws, PreferredOne does not remove a drug from coverage or make negative changes to a preferred or tiered cost-sharing status during the covered period, except when the covered drug is:
   1. Determined unsafe by the U.S. Food and Drug Administration (FDA)

   2. Removed from the market by the manufacturer

   3. Considered a statutory exclusion under EHB

   4. Needed to meet the minimum category/class counts for products subject to EHB benchmark requirements

DEFINITIONS:

Biologic (BLA):
Biologic agents are derived from natural sources (human, animal, microorganisms); these are large complex proteins applicable to the prevention, treatment, or cure of a disease or condition of human beings. Given the complexity of the drug and the difficulty to characterize a biologic, the manufacturing process is proprietary. Licensed by the Public Health Services Act (PHS) (section 351), the 351(a) pathway is utilized for the approval of biologics. Examples of biologics include: vaccine, blood products, antitoxin, allergy shots and cellular therapies.

Biosimilar ("abbreviated" BLA):

A biosimilar is a biological product that is highly similar to the reference or innovator product, notwithstanding minor differences in clinically inactive components; and there are no clinically meaningful differences between biological the product and the reference product in terms of the safety, purity, and potency of the product. Created by the Biologics Price Competition and Innovation Act (BPCIA), the 351(k) pathway streamlined the licensure of biologics demonstrated to be biosimilar to a reference product with intentions of creating a low-cost alternative to innovator biologics. A list of licensed biological products with reference product exclusivity and biosimilarity or interchangeability evaluations care be viewed in the Purple Book.

Brand and generic (NDA, ANDA):
Small molecule drugs, or conventional drugs, are pure chemical substances with a unique chemical structure. Licensed by the Food, Drug, and Cosmetic Act (FD&C Act) (section 505), conventional drug approvals occur via either NDA or ANDAs. To better illustrate the differences in each pathway, please note the following examples:

- 505(b)1: Traditional development path for brand name drugs whose active ingredient has not previously been FDA approved
- 505(b)2: Drugs with a new indication, change in dosage form, and combination products of previously FDA approved drugs
- 505(j): Generic version of a previously FDA approved drug with the same dosage form, strength, route of administration, quality, active ingredient, and intended use. Approved drug products with therapeutic equivalence evaluations can be viewed in the Orange Book.

Follow-On Biologic (NDA):
Follow-on biologic agents are highly similar to innovator biologic drugs, where the innovator biologic drug was approved via section 505 of the FD&C Act, and not through the 351(a) pathway. For example, historically hormones (ie, insulins) have been regulated as drugs, under section 505 of the FD&C Act, and not as biologics under the PHS Act. One BPCIA phase-in is complete, this pathway will no longer exist.

Formulary:
A list, which may change from time to time, of prescription drugs which, PCHP/PIC, in its sole discretion, after consideration of recommendations from PCHP/PIC Pharmacy and Therapeutics Quality Management Subcommittee, has established for use with the COC.

Formulary Enhancement:
Mid-cycle addition of a new medication or product to the formulary or mid-cycle placement of an existing medication or product to a lower cost formulary tier.

Interchangeable:
Interchangeable products are both biosimilar to an FDA-approved reference product, and can be expected to produce the same clinical result as the reference product in any given patient. An interchangeable product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

Reference product:
The single biological product licensed by the FDA under section 351(a) of the PHS Act, against which a proposed biosimilar biological product is evaluated in its biosimilar application.

Specialty Drugs:

Injectable and non-injectable *prescription drugs* as determined by PIC, or PAS which have one or more of the following key characteristics:
1. Frequent dosing adjustments and intensive clinical monitoring are required to decrease the potential for drug toxicity and to increase the probability for beneficial outcomes;
2. Intensive patient training and compliance assistance are required to facilitate therapeutic goals;
3. There is limited or exclusive product availability and/or distribution;
4. There are specialized product handling and/or administration requirements; or
5. Are produced by living organisms or their products.

REFERENCES:

1. Medical Management Process Manual UR015 Use of Medical Policy and Criteria
2. Clinical Policy: MP/C009 Coverage Determination Guidelines
3. Pharmacy Clinical Policy: PC/F002 Formulary Exceptions
4. Pharmacy Clinical Policy: PP/R001 Review of new FDA-Approved Drugs and Clinical Indications for Provider Administered Medications
5. NCQA 2021 HP Standards and Guidelines UM 11: Procedures for Pharmaceutical Management

DOCUMENT HISTORY:

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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).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

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ဟသျှဉ်ဟသး– နမ့်ကတိ၊ ကညီ ကျိာ်အယိ, နမၤန့် ကျိာ်အတ်မၤစၢၤလ၊ တလၫ်ဘူဉ်လၫ်စ့၊ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

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ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

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If you believe that PIC 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 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

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.

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