PreferredOne®

Department of Origin: Pharmacy	**Effective Date:** 02/15/2023
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	**Date Approved:** 02/15/2023
Pharmacy Clinical Policy Document: Formulary Exceptions	**Replaces Effective Policy Dated:** 12/08/2021
Reference #: PC/F002	**Page**: 1 of 7

PURPOSE:
The intent of this policy is to provide clinical guidelines for granting *formulary exceptions* when the benefit plan and formulary allows.

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:
Formulary exceptions will be allowed based on the procedures and guidelines listed below when exceptions are allowed under the prescription drug benefit.

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 Exceptions*

A. PreferredOne will check plan benefits to determine if *formulary exceptions* are allowed.

B. Requests for a *formulary exception* will be reviewed on a case-by-case basis.

C. *Formulary exceptions* for drugs removed from the *formulary* for safety or convenience reasons are not allowed.

D. A *formulary exception* may be allowed when documentation supports that the member has tried and failed two *formulary alternatives* as evidenced by at least one of the following: 1 – 3.
   1. Documented lack of, or only partial, therapeutic effect at maximal dosing; or

   2. Documented allergy or intolerable adverse effect; or

   3. Documentation of failure of *formulary alternatives* due to compliance issues, (eg, administration route and/or dosage form, frequency of dosing, etc.) that will lead to a serious deterioration in the member's condition.

E. A *formulary exception* for a *multi-source brand* drug may be allowed when documentation supports the following: 1 and 2
   1. The member has tried and failed two *formulary alternatives* as evidenced by at least one of the following: a – c
      a. Documented lack of, or only partial, therapeutic effect at maximal dosing; or
      b. Documented allergy or intolerable adverse effect; or
      c. Documented failure due to compliance issues, (eg, administration route and/or dosage form, frequency of dosing, etc.) that will lead to a serious deterioration in the member's condition; and

2. The *generic equivalent* has been attempted and documentation supports all of the following: a or b, and c
   a. The *generic equivalent* has resulted in an adverse reaction; or
   b. Has shown to be ineffective after titration to a maximally tolerated dose; and
   c. An *authorized generic* is not available.

F. The use of "co-pay assistance" outside of the prescription drug benefit or use of samples of a non-formulary drug will count as treatment when determining if a *formulary exception* can be allowed, when the drug is in a high-risk drug class and the request meets G. 1. and 2. below.

G. High-risk drug classes - an ongoing *formulary exception* may be allowed when documentation supports both of the following: 1 and 2
   1. The member has been stabilized on the drug for at least 90 days; and

   2. An interchange may cause a health risk due to the medication being in one of the following therapeutic categories along with its stated purpose: a - h
      a. Antiarrhythmics (including, but not limited to, amiodarone, disopyramide, flecainide, etc.)
      b. Anticoagulants, platelet, Factor Xa and thrombin inhibitors (including, but not limited to, warfarin, Pradaxa, Xarelto, etc.)
      c. Anticonvulsants for seizure disorders (including, but not limited to, phenytoin, carbamazepine, lamotrigine, etc.)
      d. Antidepressants for mood disorders (including, but not limited to, duloxetine, fluoxetine, venlafaxine, etc.)
      e. Antineoplastics (including, but not limited to, Piqray, capecitabine, dasatinib, etc.)
      f. *Antipsychotics* (including, but not limited to, risperidone, quetiapine, aripiprazole, etc.)
      g. Antiretrovirals (including, but not limited to, Descovy, efavirenz, zidovudine, etc.)
      h. Immunosuppressants when used for prophylaxis of organ transplant rejection; or

III. PIC, and PAS non-ERISA plans - Non-formulary *antipsychotic drugs* required coverage:

A. *Formulary exceptions* for *antipsychotic drugs:* 1 - 4
   1. *Antipsychotic drugs* will be covered at a *formulary* benefit level if prescribed to treat *emotional disturbance* or *mental illness* regardless of whether the drug is in the applicable *formulary* if the prescribing provider:
      a. Indicates to the dispensing pharmacist, orally or in writing, that the prescription must be dispensed as communicated; and
      b. Certifies in writing to PIC/PAS Non-ERISA Plan Administrator or designee, that the provider has considered all equivalent drugs in the drug *formulary* and has determined that the drug prescribed will best treat the member's condition.

   2. *Formulary exceptions* for drugs removed from the *formulary* for safety reasons are not allowed.

   3. *Formulary exceptions* authorized in this section are not subject to a special deductible, copayment, coinsurance, or other special payment requirement that the PIC/PAS Non-ERISA Plan Administrator or designee does not apply to drugs that are in the *formulary*.

4. Written certification is not required from the prescribing provider each time a prescription is refilled or renewed after the initial written certification has been received.

B. Continuing care for members receiving *antipsychotic drugs*: 1 - 3
   1. Members receiving a prescribed *antipsychotic drug* to treat a diagnosed *mental illness* or *emotional disturbance*, may continue to receive the prescribed drug for up to one year without the imposition of a special deductible, copayment, coinsurance, or other special payment requirements for both of the following: a and b
      a. The applicable *formulary* changes or the member changes health plans; and
      b. The drug has been shown to effectively treat the member's condition.

   2. To be eligible for the continuing care benefit - all of the following: a - c
      a. The member must have been treated with the drug for 90 days prior to the change in the health plan's *formulary* or a change in the member's health plan; and
      b. The health care provider prescribing the drug indicates to the dispensing pharmacist, orally or in writing, that the prescription must be dispensed as communicated; and
      c. The health care provider prescribing the drug certifies in writing to the health plan company that the drug prescribed will best treat the patient's condition.

   3. The continuing care benefit shall be extended annually (beyond the initial approval period) for both of the following: a and b
      a. The prescribing provider indicates to the PIC/PAS Non-ERISA Plan Administrator or designee indicates to the dispensing pharmacist, orally or in writing, that the prescription must be dispensed as communicated; and
      b. Certifies in writing to the health plan company that the drug prescribed will best treat the member's condition.

C. Other *formulary exceptions* for *antipsychotic* drugs will be allowed when the prescribing provider indicates to the PIC/PAS Non-ERISA Plan Administrator or designee any of the following: 1 - 3
   1. The *formulary* drug causes an adverse reaction in the member; or

   2. The *formulary* drug is contraindicated for the member; or

   3. The prescribing provider demonstrates that the prescription drug must be dispensed as written (DAW) to provide maximum medical benefit to the member.

IV. Drugs developed pre-1938, that are marketed in the United States but do not have required FDA approval, will be assessed for *formulary exception* on a case-by-case basis.

PROCEDURE:
Initiation of a *formulary exception* request

I. The drugs that are affected by *formulary* programs are dependent on the prescription drug benefit and Pharmacy Benefit Manager (PBM). Members and providers may identify what drugs and/or drug classes fall into *formulary* program requirements by:

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

B. Accessing www.preferredone.com (see formularies under the pharmacy information section) or the applicable PBM's website (https://www.preferredone.com/pharmacy-information/formulary/).

II. Formulary exception requests can be initiated by the member (or member's designee), or prescribing physician (or other prescribing provider as appropriate) by the following:

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

B. In writing or by facsimile by completing the Minnesota Uniform Formulary Exception Form (also found on the PreferredOne Pharmacy Resources page); or

C. For providers only: Electronically by completing the online Medication Request Form (also found on the PreferredOne Pharmacy Resources page); or

D. For members with individual plans only: Completing the online formulary exception request form available through the member's login at www.preferredone.com.

III. Circumstances are determined to be *exigent* when documentation supports all of the following: A – C

A. That an *exigency* exists based on the following: 1 or 2
1. The member is suffering from a health condition that may seriously jeopardize the enrollee's life, health, or ability to regain maximum function; or

2. The member is undergoing a current course of treatment using a non-formulary drug; and

B. The basis for the *exigency* (that is, the harm that could reasonably come to the member if the requested drug were not provided within the timeframes specified by the issuer's standard drug exceptions process); and

C. Justification supporting the need for an exception to treat the member's condition, including a statement that all covered *formulary* drugs on any tier will be or have been significantly less effective as the non-*formulary* drug, or would have adverse effects.

IV. Timeframes for completion and duration of approval of a *formulary exception*:

A. Expedited exception requests that are determined to have *exigent* circumstances will be completed within 24 hours of receipt of complete information and will be approved for the duration of the exigency; or

B. Expedited exception requests that are determined to have non-exigent circumstances will be completed within 48 hours (including one business day) and will be approved for up to 12 months; or

C. Standard exception requests will be completed within 72 hours of receipt of complete information and will be approved for up to 12 months.

V. Notification method and process after completion of a *formulary exception* request:

A. If a *formulary exception* request is approved:
1. An override will be entered in the PBM processing system to allow adjudication of the prescription for coverage of the *non-formulary* drug at the highest cost tier formulary benefit level; and

2. Notification of the approval will be provided promptly to the attending health care professional and hospital or physician office as applicable by telephone, facsimile to a verified number or by electronic mail to a secure electronic mailbox; and

3. Written notification will be provided to the member and to the attending health care professional and hospital or physician office as applicable.

B. If a *formulary exception* request is not approved:
1. Notification of the denial and appeal rights will be provided within the time period specified in section IV. by telephone, facsimile to a verified number, or by electronic mail to a secure electronic mailbox within one working day after making the determination to the attending health care professional and hospital or physician office as applicable; and

2. Written notification of the denial and appeal rights will be provided to the member and to the attending health care professional and hospital or physician office as applicable.

VI. External exception request review for denial of an expedited or standard exception request

A. The member, member's designee or the prescribing provider may request a review by an independent review organization; and

B. Timeframes for completion are based on the status of the original request.
1. Expedited review requests based on exigent circumstances will be completed within 24 hours of receipt of complete information; or

2. All other requests will be completed within 72 hours of receipt of complete information.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description.

DEFINITIONS:
Antipsychotic Drugs:
A class of medicines used to treat psychosis and other mental and emotional conditions.

Authorized Generic: An approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic may be marketed by the brand name drug company, or another company with the brand company's permission.

Closed Formulary:
A closed formulary is a pharmacy benefit plan that only allows coverage of drugs listed on the formulary. In this type of pharmacy plan there are no non-formulary pharmacy benefits unless the plan authorizes a *formulary exception.*

Emotional Disturbance:
An organic disorder of the brain or a clinically significant disorder of thought, mood, perception orientation, memory, or behavior that seriously limits a child's capacity to function in primary aspects of daily living such as personal relations, living arrangements, work, school, and recreation.

Exigent Circumstance:
When a member is suffering from a health condition that may seriously jeopardize the member's life, health, or ability to regain maximum function or when a member is undergoing a current course of treatment using a non-formulary drug.

Formulary:
A list, which may change from time to time, of preferential *prescription drugs* that is used by the Plan.

Formulary alternative: Drug products with different chemical structures but which are of the same pharmacological and/or therapeutic class and can be expected to have similar therapeutic effects and adverse reaction profiles when administered to patients in therapeutically equivalent doses.

Formulary exception:
In a *closed* or *open formulary***,** a formulary exception is allowing coverage of a *non-formulary* drug at the highest cost tier formulary benefit level.

Generic Equivalent: a drug that is identical—or bioequivalent—to a brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use, that which can be substituted equally for its brand-name counterpart based on approval through an abbreviated new drug application (ANDA) by the Food and Drug Administration (FDA).

Mental Illness:
An organic disorder of the brain or a clinically significant disorder of thought, mood, perception orientation, memory, or behavior and seriously limits a person's capacity to function in primary aspects of daily living such as personal relations, living arrangements, work, and recreation.

Multi-source brand:
A multi-source brand drug is a brand name drug that is marketed or sold by two or more manufacturers or labelers, is no longer protected under patent exclusivity, and has a therapeutically equivalent generic alternative available.

Non-formulary:
A drug that is covered at the non-formulary benefit level.

Open formulary:
An open formulary is a pharmacy plan where the member has benefits for non-formulary drugs but typically at a higher copayment or coinsurance.

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Reference #: PC/F002	**Page**: 7 of 7

Prescription drugs:
A drug approved by the FDA for use only as prescribed by a provider properly authorized to prescribe that drug.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Generic Drugs: Questions & Answers. Current as of 12/1/2021. Retrieved from https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers
3. Medical Policy: MP/C009 Coverage Determination Guidelines
4. Pharmacy Clinical Policy: PP/Q003 Quantity Limits
5. Pharmacy Clinical Policy: PP/S001 Step Therapy
6. Minnesota Statute 62Q.527 Nonformulary Antipsychotic Drugs; Required Coverage.
7. U.S. Government Printing Office. 45 CFR 156.122. Current as of 11/24/2021. Retrieved from http://www.ecfr.gov/cgi-bin/text-idx?SID=7242944c09ce9657251ab87a6a26be0c&node=se45.1.156_1122&rgn=div8. Accessed 01-25-21.
8. Minnesota Session Laws - 2020, Regular Session. Current as of 11/24/2021. Retrieved from https://www.revisor.mn.gov/laws/2020/0/114/
9. NCQA 2020 HP Standards and Guidelines UM 5: Timeliness of UM Decisions
10. NCQA 2020 HP Standards and Guidelines UM 11: Procedures for Pharmaceutical Management

DOCUMENT HISTORY:

Created Date: 11/24/2021
Reviewed Date: 11/24/2022
Revised Date:

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

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

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

ဟသျှဉ်ဟသး– နမ့်ကတိ၊ ကညီ ကျိာ်အယိ, နမၤန့် ကျိာ်အတ်မၤစၢၤလ၊ တလၫ်ဘူဉ်လၫ်စ့၊ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 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 ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។

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).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

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

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

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- Information written in other languages

If you need these services, contact a Grievance Specialist.

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.

Language Assistance Services

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ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

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

ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 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 ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

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).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).