



Department of Origin: Pharmacy	Effective Date: 02/15/2023
Approved by: Chief Medical Officer	Date Approved: 02/15/2023
Pharmacy Clinical Policy Document: Quantity Limits	Replaces Effective Policy Dated: 03/08/2022
Reference #: PP/Q003	Page: 1 of 3

PURPOSE:

The intent of this pharmacy clinical policy is to provide coverage guidelines for quantity limits.

Quantity limits (QL) is a method employed by pharmacy benefit managers (PBM) and health plans to provide a high-quality and cost-effective prescription drug benefit. It ensures that the quantity of units supplied in each prescription remains consistent with clinical dosing guidelines and the health plan's benefit design.

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 *quantity limit* requirement for specific drug classes. For certain indications, if *reliable evidence* supports dosing over the FDA approved dosing, a *quantity limit* override may be allowed. QL for controlled substances, such as but not limited to opioids, are managed in accordance with federal and state regulations. Approval of a *quantity limit* override 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 step therapy (see Pharmacy Clinical Policy: PP/S001 Step Therapy). 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 the provider prescribes a quantity of a medication more than the current *quantity limit* allows, a reject message is sent to the pharmacy.
- II. Clinical review for a *quantity limit* override is necessary when the prescribing provider feels the higher quantity is appropriate.
- III. A *quantity limit* override may be allowed for one of the following: A or B
 - A. The member has had an inadequate response to the medication at the established quantity limit and *reliable evidence* supports the efficacy and safety at the requested dose; or
 - B. The member's history of use has shown a therapeutic response to a dose/quantity greater than the QL.
- IV. When a generic is available for a listed brand name medication, the QL will apply to both the generic and the brand.



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EXCLUSIONS (not limited to):

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

DEFINITIONS:**Quantity Limit (QL):**

A defined amount allowed of a drug per prescription per co-payment based on the U.S. Food and Drug Administration (FDA) approved dosing guidelines, regulatory agencies, and/or the health plans' benefit requirements.

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.

BACKGROUND:

Some dispensed prescription drugs require the use of quantity limits, which ensure that the quantity of each prescription remains consistent with clinical guidelines. Quantity limits can apply to formulary or non-formulary drugs and brand or generic drugs. The member will be responsible for additional coinsurance for quantities received more than the quantity limit.

Maximum quantity per prescription is usually set to support the maximum dose recommended by the FDA. However, the QL may be rounded up or down to accommodate the manufacturer's product packaging.

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REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Medical Policy: MP/C009 Coverage Determination Guidelines
3. Medical Policy: MP/L004 Levels Evidence and the Evaluation of Health Care Services
4. Pharmacy Clinical Policy: PC/F002 Formulary Exceptions
5. Pharmacy Clinical Policy: PP/S001 Step Therapy
6. Pharmacy Clinical Policy: PP/O001 Off-Label Drug Use
7. Minnesota Statute 62M.05 Procedures for Review Determination
8. Minnesota Statute 62A.3095 Prescription Eye Drops Coverage
9. NCQA 2021 HP Standards and Guidelines
 - UM 5: Timeliness of UM Decisions
 - UM 11: Procedures for Pharmaceutical Management

DOCUMENT HISTORY:

Created Date: 09/02/15 (previously part of PP/Q001 and PP/Q002)
Reviewed Date: 09/02/16, 09/01/17, 08/31/18, 01/29/19, 01/24/20, 01/08/21, 12/27/2021, 11/30/2022
Revised Date: 11/29/18

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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, taiaajiila qarqaarsa 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).

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

ဟ်သုာ်ဟ်သး- နမာ်ကတိ၊ ကညီ ကိာ်အယံ၊ နမာ် ကိာ်အတၢ်မၤစၢၤလၢ တလၢာ်ဘၣ်လၢာ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. 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។ ចរ 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.

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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
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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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