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Medication Policy Manual | **Policy No:** dru536

Topic: Quantity Limit Exceptions | **Date of Origin:** December 16, 2016

Committee Approval Date: October 2, 2025 | **Next Review Date:** 2026

Effective Date: January 1, 2026

IMPORTANT REMINDER

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medication policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

DESCRIPTION

- Quantity limits (QLs) are the maximum number of doses of medication that may be covered in a given time period, such as tablets per month.
- The formulary listing allows for maximal allowable doses over a given time (usually specified as a given quantity of the dosage form per 28-30 days) based on safety and/or cost.
- The intent of this policy is to allow for consideration of coverage for quantities in excess of QLs specified in the formulary listing or in drug-specific medication coverage policies.
- However, this policy does not apply to medications with a drug-specific medication policy that has its own specific quantity limit criteria built into that policy.
- This policy only applies to medications under the pharmacy benefit; it does not apply to medications under the medical benefit.

PLEASE NOTE: Specific pre-authorization (PA) criteria and QLs in drug-specific medication policies take precedence over the general criteria listed in this policy**.**

Policy/Criteria

Most contracts require pre-authorization approval of Quantity Limit (QL) Exceptions prior to coverage.

I. Continuation of therapy (COT): Medication dosages, quantities, and durations above the QL may be considered medically necessary for COT when criteria A through C below are met.

A. The patient is established on this therapy AND one of the following situations applies (criterion 1 or 2 below):

1. Prior to current health plan membership AND the medication quantity was covered by another health plan.

OR

2. The medication AND the medication quantity was initiated for acute disease management, as part of an acute unscheduled, inpatient hospital admission AND there is clinical benefit.

AND

B. The requested medication is not contained within a policy listed in *Table 1*.

AND

C. The prescribed dose cannot be achieved with a lower quantity (that does not exceed the QL) of a commercially available higher strength dosage form.

Please note: *Medications obtained as samples, coupons, or promotions, paying cash for a prescription ("out-of-pocket") as an eligible patient, or any other method of obtaining medications outside of an established health plan benefit (from your insurance) does NOT necessarily establish medical necessity. Medication policy criteria apply for coverage, per the terms of the member contract with the health plan.*

II. New starts (treatment-naïve patients): Medication dosages, quantities, and durations above the QL may be considered medically necessary when criteria A through E below are met:

A. The requested medication is not contained within a policy listed in *Table 1*.

AND

B. The prescribed dose cannot be achieved with a lower quantity (that does not exceed the QL) of a commercially available higher strength dosage form.

AND

C. The maximal doses specified under the QL (as in the formulary listing or drug-specific medication policy) have been tried and deemed ineffective or there is clinical support (e.g., clinical literature, patient attributes, or characteristics of the drug) that the number of doses available under the QL would be ineffective.

AND

D. There is a specific documented clinical rationale for the requested dosage, quantity, or duration of medication.

AND

E. The requested dosage, quantity, or duration is safe and effective as documented in peer-reviewed medical literature (such as randomized controlled trials), accepted standards of medical practice, and/or in Compendia [i.e., American Hospital Formulary Service (AHFS), Thomson Reuters (Healthcare) Micromedex/ DrugDex, Elsevier Gold Standard's Clinical Pharmacology, National Comprehensive Cancer Network Drugs and Biologics (NCCN)].

III. Limitations and Authorization Period:

A. Authorization **may** be renewed at least annually. Clinical documentation (such as chart notes) must be provided to confirm that current medical necessity criteria are met, and that the medication is providing clinical benefit, such as disease stability or improvement.

PLEASE NOTE: If the requested medication has a pre-authorization policy with a more stringent authorization period in place, those policy limits will apply.

IV. Dosages above the quantity limit (QL) not meeting coverage criteria above are considered not medically necessary.

V. Dosages above the quantity limit (QL) not meeting coverage criteria above are considered investigational.

Table 1: Policies with specific QL Criteria:

Policy	Policy Title
dru073	transmucosal immediate-release fentanyl containing medications (TIRFs)
dru093	Sodium oxybate-containing medications
dru151	Nilotinib-Containing Products
dru385	Complement Inhibitors, FOLLOWING PRODUCTS ONLY: • Empaveli (pegcetacoplan) • Tavneos (avacopan)
dru405	metyrosine (generic, Demser)
dru410	Xifaxan, rifaximin
dru444	Drugs for Chronic Inflammatory Diseases
dru493	Monoclonal antibodies for skin and other inflammatory conditions
dru515	Extended-release (ER) Opioid Medication Products for Pain
dru517	New to Market Drugs and Indications
dru535	Medications for Hereditary Angioedema (HAE)
dru538	Monoclonal Antibodies for Asthma and Other Immune Conditions
dru539	Hemlibra, emicizumab-kxwh
dru548	Non-preferred testosterone replacement therapy products
dru549	Blood Factors for Hemophilia A, high-cost extended-half-life products
dru550	Blood Factors for Hemophilia B, extended-half-life products
dru551	Medications for Phenylketonuria (PKU)
dru569	Epidiolex, cannabidiol
dru598	Medications for Thrombotic Thrombocytopenic Purpura (TTP), FOLLOWING PRODUCT ONLY: • Cablivi (caplacizumab-yhdp)
dru612	Anabolic Bone Medications
dru626	High-cost medications for erectile dysfunction
dru656	Enspryng, satralizumab-mwge
dru668	Medications for Primary Hyperoxaluria, FOLLOWING PRODUCT ONLY: • Rivfloza
dru699	Ileal Bile Acid Transporter (IBAT) Inhibitors
dru801	Voranigo, vorasidenib
dru806	Non-Factor Hemophilia A and B Prophylactic Products
dru808	Orlynvah, sulopenem etzadroxil/probenecid

References

1. American Hospital Formulary Service (AHFS): http://www.ahfsdruginformation.com/
2. Thomson Reuters (Healthcare) Micromedex/ DrugDex: DRUGDEX System [database online]. Greenwood Village, CO: Truven Health Analytics. http://www.micromedexsolutions.com/.http://www.micromedexsolutions.com/micromedex2/librarian#.
3. Elsevier Gold Standard's Clinical Pharmacology: Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc. http://clinicalpharmacology-ip.com.
4. National Comprehensive Cancer Network Drugs and Biologics (NCCN): National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/f_guidelines.asp.

Revision History

Revision Date	Revision Summary
10/2/2025	Updated Table 1 with the following: Added: • dru668, Medications for Primary Hyperoxaluria (Rivfloza only) • dru801, Voranigo, vorasidenib • dru806, Non-Factor Hemophilia A and B Prophylactic Products • dru808, Orlynvah, sulopenem etzadroxil/probenecid Removed: • dru145, lapatinib (generic, Tykerb) – UM removed and policy archived. • dru199, Votrient, pazopanib – UM removed and policy archived. • dru741, Medications for recurrent Clostridioides difficile infection (rCDI). Specific QL guidelines in policy. • dru773, Medications for molluscum contagiosum. Specific QL guidelines in policy. Updated (policy name changes); • dru151, Nilotinib-Containing Products • dru493, Monoclonal antibodies for skin and other inflammatory conditions
4/3/2025	Removed Appendix 1 "Operational criteria for QL Only plans" as it no longer reflects our intent. QL only policy plans are to follow individual policy specified QL.
9/19/2024	Updated Table 1: - Added dru741, Medications for recurrent Clostridioides difficile infection (rCDI). - Added dru773, Medications for molluscum contagiosum. - Updated policy title for dru598 to Medications for Thrombotic Thrombocytopenic Purpura (TTP). Policy previously called Cablivi, caplacizuamab-yhdp. - Removed archived dru233, Egrifta, tesamorelin. - Removed archived dru176, tetrabenazine (generic, Xenazine).

Revision Date	Revision Summary
9/14/2023	No criteria changes with this annual review.
6/15/2023	• Removed the following from Table 1: - dru134 Nexavar, sorafenib (policy archived). - dru587 Coverage Exception Criteria for Erectile Dysfunction Medications (policy archived). - dru599 Direct Acting Antivirals for HCV (policy archived). - Specified products listed for dru444 Drugs for chronic inflammatory diseases. - Specified products listed for dru538 Monoclonal Antibodies for Asthma and Other Immune Conditions. • Added the following to Table 1: - dru548 Non-preferred testosterone replacement therapy products (quantities above the listed quantity limits are considered not medically necessary per policy).
12/9/2022	• Updated Table 1: - Added dru145 lapatinib (generic, Tykerb). - Added Tavneos (avacopan) to dru385. - Removed dru417 trientine (generic, Syprine). • No criteria changes with this annual update.
9/23/2022	Added dru656 Enspryng, satralizumab-mwge to Table 1 (effective 10/15/2022).
3/18/2022	• Added the following medication policies to Table 1: - dru699 Ileal Bile Acid Transporter (IBAT) Inhibitors • Removed the following medication policy from Table 1: - dru407 Repatha, evolocumab
10/15/2021	• No criteria changes with this annual update. • Medications added from dru444 in Table 1 include Cimzia (certolizumab), Cosentyx (secukinumab), and Stelara (ustekinumab). • Added dru538 Monoclonal Antibodies for Asthma and Other Immune Conditions to Table 1. • Added Empaveli (pegcetacoplan) from dru385, Complement Inhibitors.
4/21/2021	• Removed Otezla (apremilast) from Table 1. It is now placed in dru444, Drugs for chronic inflammatory diseases. • Requests for over QL on Otezla (apremilast) can be handled by dru536.
1/1/2021	• Added continuation of therapy (COT) criteria (no change to intent of coverage criteria). • Updated Table 1 to be consistent across policy catalog. Added operational criteria for QL Only plans.
4/22/2020	Updated Table 1 to include: Arzerra, Gazyva, Spinraza, Luxturna, Hemlibra, Hemophilia A & B Blood Factors, Gamifant, Zolgensma, High-Cost Medication for Erectile Dysfunction, Provider-Administered Drugs from CID, Tepezza, Palforzia. Removed vardenafil-containing medications, and tadalafil-containing medications (archived).

Revision Date	Revision Summary
1/22/2020	• Removed Afinitor from Table 1. • Requests for Afinitor over QL in policy will now be handled through this quantity limit policy. • Added Xenazine policy to Table 1, as there is specific over QL requirements in policy.
10/23/2019	Removed Forteo and Tymlos from policy list, replaced with new Anabolic Bone Meds policy.
7/24/2019	• Updated Table 1 by removing individual medications and replacing with specific policies. • Removed Ilaris, Demser, Arcalyst, Viagra, Xyrem, and Veltassa/ Lokelma as these policies do not have over QL specific criteria in policy.
8/17/2017	Added additional products to Table 1. (Lokelma, Kuvan, Palynziq).
2/16/2018	Clarified description. Added dose consolidation question. Updated medications included in Table 1.
8/11/2017	No criteria changes with this annual update.

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