

Clinical Pharmacy Program Guidelines for Quantity Limits

Program	Prior Authorization
Medication	Quantity Limits
Markets in scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

The UnitedHealthcare Community Plan formularies/Preferred Drug Lists (PDLs) intend to provide the highest quality of care while also containing cost. Therefore, the UnitedHealthcare Community Plan formularies / PDLs will, in part, be administered through a quantity limit process.

UnitedHealthcare Community Plan requires prior authorization to use drugs at a level of service beyond formulary quantity limits. Many medically necessary drugs have clinically accepted dosing guidelines, and dosing regimens can often be consolidated to make them more efficient. This policy will identify patients that are prescribed medication that is indicated for a specific dosing guideline and/or dosed according to product labeling, but may not be taking the most efficient dosage regimen. This policy will also identify patients that are prescribed a quantity of medication that is greater than the labeling would indicate. This policy will ensure consolidation of medication dosage to the most efficient dosage regimen, as well as appropriate dosing according to product labeling.

UnitedHealthcare Community Plan applies quantity limits to formulary/PDL medications that are amenable to the development of clinically appropriate, rational dosing guidelines. This procedure helps to monitor utilization, promote high quality cost-effective care, and enhances formulary compliance and appropriate prescribing. Eligibility for approval of requests exceeding formulary quantity limits is based upon medical necessity.

Examples of quantity limits:

(1) Amlodipine 10mg daily can be achieved with two 5mg tabs or one 10mg tab. The more cost effective option is one 10mg tab. Therefore, a quantity limit of 30 tabs / month is applied to the 5mg tablets.

(2) Strattera is indicated for once or twice daily dosing. The more efficient regimen is once daily. Therefore, a quantity limit of 30 caps / month is applied to Strattera. If

Strattera once daily is ineffective or not tolerated, the Plan can be contacted for a Medical Exception.

Certain medications that are subject to high utilization will have a four prescription limit per month to prevent misuse/abuse. This affects the following classes of medication: migraine therapy, benzodiazepines, and muscle relaxants.

Certain topical products are subject to limits per fill and/or per month. This policy addresses request to exceed those limits.

2. Coverage Criteria:

A. A request for a quantity of medication that exceeds the quantity limit will be approved based on all of the following criteria:

1. **One** of the following:

a. The requested drug must be used for an FDA-approved indication

-OR-

b. The use of this drug is supported by information from the appropriate compendia of current literature*

-AND-

2. The drug is being prescribed within the manufacturer's published dosing guidelines or falls within dosing guidelines found in the compendia of current literature*

-AND-

3. The requested dosage cannot be achieved using the plan accepted quantity limit of a different dose or formulation.

-AND-

4. The drug is being prescribed for a medically accepted indication that is recognized as a covered benefit by the applicable health plans' program.

Authorization will be issued for 12 months.

*Compendia of Current Literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and

Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology • United States Pharmacopoeia-National Formulary (USP-NF)

B. A request for a quantity of medication that exceeds the quantity limit for the treatment of gender dysphoria will be approved based on all of the following criteria:

1. The use of this drug is supported by information from the appropriate compendia of current literature*

-AND-

2. The drug is being prescribed for an indication that is recognized as a covered benefit by the applicable health plans' program.

Authorization will be issued for 12 months.

If the above criteria are not met, then refer for clinical review by an appropriate trained professional (physician or pharmacist) based on the applicable regulatory requirement.

*Compendia of Current Literature: • American Hospital Formulary Service Drug Information • National Comprehensive Cancer Network Drugs and Biologics Compendium • Thomson Micromedex DrugDex • Clinical Pharmacology • United States Pharmacopoeia-National Formulary (USP-NF)

C. For requests exceeding the monthly migraine therapy, benzodiazepines, or muscle relaxants prescription limit:

1. Medical necessity rationale provided for why the member requires 5 or more fills of the same drug or drug class within a month.

Authorization will be issued for 1 month (If deemed medically necessary, longer authorization duration is permitted).

D. For topical products exceeding the allowable package size per fill OR the allowable quantity per month:

1. The physician attests that a larger quantity is needed for treatment of a larger surface area.

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Program	Program type – Prior Authorization
Change Control	
Date	Change
6/2009	Combined previously approved quantity limits for AmeriChoice of Pennsylvania and Unison MedPlus. Additional quantity limits added for Risperdal Consta, Suprax 400mg tablets, Toradol, Lamisil, Ovide, Diflucan, and modification of Zithromax quantity limits. Policy reformatted.
3/2010	Removed 90/180 days supply in 365 days treatment duration quantity limit for nicotine replacement products (Nicoderm CQ, Nicorette Gum, Nicotrol Inhaler, and Nicotrol Nasal Spray). Monthly quantity limits remain.
3/2010	Added quantity limit of 1 injection/month for Invega Sustenna
6/2010	Changed Zofran 4,8 mg tabs and ODT quantity limit to 30 tablets per fill and 90 tablets per month
12/2010	Increased Aricept 10 mg tab from 30 tablets/month to 60 tablets/month. Added Adrenaclick and Twinject quantity limit of 2 syringes/month.
6/2011	Annual Review
12/2011	Added Vyvanse, Onfi, Uroxatral, Flomax to quantity limit list.
12/2012	Removed quantity limit table and embedded the quantity limit database.
4/2016	Updated the quantity limit database.
2/2017	Added gender dysphoria section. Added section for requests exceeding the monthly controlled substances prescription limit. Updated policy template. Revised background section. Added topical products quantity limit section.

3/2017	<p>Updated section A to allow for an FDA approved diagnosis OR compendia supported diagnosis to be approved.</p> <p>Updated section A to require that the requested dose be within dosing guidelines AND cannot be achieved using plan accepted quantity limits.</p>
8/2018	Annual review. No changes.
8/2019	Updated background. Updated list of compendia of current literature.
8/2020	Annual review, added additional clinical rules statement.