PREMERA | BLUE CROSS

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY POLICY – 5.01.656

Drug Quantity Management

Effective Date:	Sep. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Aug. 12, 2025	
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

A quantity limit is the amount of a specific drug that can be approved for a specific time period. Quantity limits are set to promote safe and appropriate use of medications. The quantity limits in this policy are based on current US Food and Drug Administration (FDA) and manufacturer dosing guidelines and current medical best practices. This policy includes information about many different types of drugs and the quantity in which they may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Target Drugs (See Appendix)	**The Target Drug(s) may be considered medically necessary when the dose is within the US Food and Drug Administration (FDA) labeled dosing.**

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for all drugs listed in the policy may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for all drugs listed in policy may be approved up to 12 months as long as the drug-specific coverage criteria are met.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation and medication history

Coding

N/A

Related Information

Definition of Terms

Label: Product label refers to the FDA approved prescribing information that is available for every legend drug approved for use in the US. The label includes indications, contraindications, recommended dosing, warnings, precautions, side effects, drug interactions and information on safety in pregnancy and other special populations. The drug's pharmacology, pharmacokinetics,

and available dosage forms are also provided. The current format also includes a summary of the pivotal clinical trials that were submitted to FDA in support of the New Drug Application. This prescribing information is included as a package insert with the product and is available on the manufacturer's website.

Quantity limits: A quantity limit is the maximum amount of a medication that may be dispensed during a given calendar period or at one prescription fill without an exception request. Dispensing of a larger quantity may be approved, based on individual case review. A specified larger quantity may be approved when individual-specific circumstances require it, or when published clinical evidence supports a higher dose protocol.

Note: Dispensing quantity limits are not intended to apply in circumstances where logistics may dictate otherwise. These circumstances include but are not limited to member vacation or business travel, disruption of normal prescription supply chains due to adverse weather events or other disasters and members living in remote areas where travel to the nearest pharmacy may sometimes be problematic.

Benefit Application

The drugs in this policy that are managed through the pharmacy benefit.

Evidence Review

Rationale

Quantity limits in this policy are based on the maximum or recommended FDA approved dose as stated in the product label. These limits represent the recommended or upper bound of the dose range that has been shown to balance safety and efficacy as demonstrated by clinical trial data contained in the New Drug Application (NDA) or supplemental application (sNDA) for higher labeled dosing. Quantities in excess of the limits in this policy may be approved based on adequate evidence from published peer reviewed clinical studies.

References

1. 21 CFR 201.5: Labeling Requirements for Prescription Drugs. Adequate Directions for Use. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201. Accessed February 11, 2025.

Appendix

Brand Name	Generic Name	Strength	Dose	Route	Quantity Amount	Day Supply
Anoro ellipta	Umeclidinium brm/ vilanterol tr	62.5-25mcg	Blister, with inhalation device	Inhalation	60	30
Arbli	Losartan potassium	10 mg/ml	Suspension, oral (final dose form)	Oral	300	30
Bucapsol	Buspirone hcl	10 mg	Capsule	Oral	120	30
Bucapsol	Buspirone hcl	15 mg	Capsule	Oral	120	30
Bucapsol	Buspirone hcl	7.5 mg	Capsule	Oral	60	30
Edurant ped	Rilpivirine hcl	2.5 mg	Tablet for suspension	Oral	180	30
Hemiclor	Chlorthalidone	12.5 mg	Tablet	Oral	30	30
Inzirqo	Hydrochlorothiazide	10 mg/ml	Suspension, reconstituted, oral (ml)	Oral	300	30
Memantine hcl-donepezil hcl er	Memantine hcl/donepezil hcl	14mg-10mg	Capsule sprinkle, extended release 24 hr.	Oral	30	30
Memantine hcl-donepezil hcl er	Memantine hcl/donepezil hcl	21 mg-10mg	Capsule sprinkle, extended release 24 hr.	Oral	30	30
Memantine hcl-donepezil hcl er	Memantine hcl/donepezil hcl	28 mg-10mg	Capsule sprinkle, extended release 24 hr.	Oral	30	30
Rivaroxaban	Rivaroxaban	2.5 mg	Tablet	Oral	60	30

Brand Name	Generic Name	Strength	Dose	Route	Quantity Amount	Day Supply
Umeclidinium-vilanterol	Umeclidinium brm/vilanterol tr	62.5-25mcg	Blister, with inhalation device	Inhalation	60	30
Xarelto	Rivaroxaban	10 mg	Tablet	Oral	60	30
Xarelto	Rivaroxaban	15 mg	Tablet	Oral	60	30
Xarelto	Rivaroxaban	2.5 mg	Tablet	Oral	60	30
Xarelto	Rivaroxaban	20 mg	Tablet	Oral	60	30

History

Date	Comments
09/01/25	New policy, approved August 12, 2025. This policy includes targeted drugs that may be considered medically necessary when the dose prescribed aligns with the United States Food and Drug Administration labeled dosing.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.