

Pharmacy Management Drug Policy

SUBJECT: Quantity Limit
POLICY NUMBER: PHARMACY-43
EFFECTIVE DATE: 01/2000
LAST REVIEW DATE: 03/20/2024

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	<input checked="" type="checkbox"/> Commercial Group (e.g., EPO, HMO, POS, PPO)	<input type="checkbox"/> Medicare Advantage
	<input checked="" type="checkbox"/> On Exchange Qualified Health Plans (QHP)	<input type="checkbox"/> Medicare Part D
	<input checked="" type="checkbox"/> Off Exchange Direct Pay	<input checked="" type="checkbox"/> Essential Plan (EP)
	<input type="checkbox"/> Medicaid & Health and Recovery Plans (MMC/HARP)	<input checked="" type="checkbox"/> Child Health Plus (CHP)
	<input type="checkbox"/> Federal Employee Program (FEP)	<input type="checkbox"/> Ancillary Services
	<input type="checkbox"/> Dual Eligible Special Needs Plan (D-SNP)	

DESCRIPTION:

Drug use management programs are implemented to ensure that members receive clinically appropriate and medically necessary prescription drugs. One such use management program focuses on quantity limits. Quantity limits are imposed on many drugs and can be defined on a monthly or a yearly limit. Quantity limits are based on:

- FDA recommended guidelines **OR**
- Standards of clinical practice **OR**
- Dose efficiency which recommends the use of a single higher strength drug rather than two (2) lower strength drugs

The prior authorization process allows physicians to submit exception requests for review where they feel there is a clinical need for the dose being prescribed. Quantities exceeding the imposed quantity limit level may create safety concerns or inappropriate utilization issues. These requests will be reviewed based on policy guidelines below.

Also reference the Clinical Review Prior Authorization policy and drug specific policies for quantity limits that are part of the prior authorization criteria.

ANESTHETICS

Drug	Quantity Limitation
ZTLido	Covered for a maximum of 30 patches per 30 days. A quantity of up to 90 patches per 30 days will only be granted for a diagnosis of post-herpetic neuralgia (PHN) AND there is a clinical need to apply the medication to a larger area. All other quantity limit requests for all other diagnoses will be denied as off-label.

ANTI-ADDICTION/SUBSTANCE ABUSE TREATMENT AGENTS

Drug	Quantity Limitation
Chantix, varenicline	Covered for a maximum of 180 days of continuous therapy within a rolling 12-month period

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ANTICONVULSANTS				
Drug		Quantity Limitation		
Nayzilam		Covered for a maximum of 5 packages per 30 days <ul style="list-style-type: none"> • Nayzilam: 10/30 (package size of 2) • Diastat/Diazepam Rectal Gel: 5/30 (package size of 1) • Valtoco: 10/30 (package size of 2) FDA labeling recommends that these medications be used to treat no more than 5 episodes per month and no more than 1 episode every 5 days for Diastat/Diazepam/Valtoco and every 3 days for Nayzilam.		
Diastat, Diazepam Rectal Gel				
Valtoco				
ANTIINFECTIVES				
Alinia		Covered for a maximum of: <ul style="list-style-type: none"> • 500mg tablet: 20 tablets per 30 days • 100mg/5ml suspension: 150ml per 30 days <u>Exception:</u> Immunocompromised patients (e.g., transplant patients, HIV patients) with a diagnosis of Cryptosporidiosis caused by Cryptosporidium species, a total quantity of up to 42 tablets or 1,080 ml of suspension may be approved. This will allow for the recommended treatment of 500 mg two times daily for 21 days.		
ANTIMIGRAINE AGENTS				
Drug		Generic Counterpart	Quantity Limits per # of days	
Amerge		Naratriptan	18 tablets	28
Almotriptan			12 tablets	28
Elyxib 120 mg/4.8 mL Oral Solution			6 bottles (28.8 mL)	30
Frova		Frovatriptan	9 tablets	28
Imitrex Tablets		Sumatriptan Tablets	18 tablets	28
Imitrex 5 mg Nasal Spray		Sumatriptan 5 mg Nasal Spray	18 units	30
Imitrex 20 mg Nasal Spray		Sumatriptan 20 mg Nasal Spray	12 units	30
Imitrex Injection (all forms)		Sumatriptan Injection (all forms)	10 injections	30
Maxalt		Rizatriptan	24 tablets	28
Maxalt MLT		Rizatriptan ODT	24 tablets	28
Onzetra			8 doses /16 nosepieces	30
Relpax		Eletriptan	12 tablets	28
Tosymra			6 units	30
Treximet		Sumatriptan/Naproxen	9 tablets*	28
Zembrace Symtouch			12 injections	30
Zomig		Zolmitriptan	12 tablets	28
Zomig MLT		Zolmitriptan ODT	12 tablets	28
Zomig Nasal Spray		Zolmitriptan Nasal Spray	12 sprays	30
Cambia 50 mg Powder Packet		Diclofenac Potassium 50 mg powder packet	9 packets	30
A quantity exception may be granted if the following criteria is met, and the exception may be granted for limited time periods depending on the patient's clinical situation: <ul style="list-style-type: none"> • The patient must be followed by a neurologist or headache specialist AND • The patient must be currently using a medication (beta blocker, tricyclic, anticonvulsant) for headache prophylaxis AND • The patient must have been evaluated for the possibility of rebound headache (or medication overuse headache) 				
*Please note: Treximet and generic sumatriptan/naproxen must be dispensed and stored in the original container and cannot be repackaged; therefore, quantity requests that satisfy the above criteria will be approved in multiples of 9 tablets				

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BEHAVIORAL HEALTH	
Drug	Quantity Limit per 30 days
Wellbutrin XL 150 mg tablet	30 tablets
<p>A quantity exception may be granted to obtain a daily dose of 450 mg if the following criteria is met:</p> <ul style="list-style-type: none"> • Must have had serious side effects or drug failure of bupropion XL 150 mg AND bupropion XL 450 mg <ul style="list-style-type: none"> ○ A daily dose of 450 mg using bupropion XL 150 mg tablets may be obtained by ordering bupropion XL 150 mg tablets, taken as 3 tablets once daily ○ Requests for a daily dose of 300 mg (2-150 mg tablets) will be reviewed using the dose efficiency criteria listed in the policy guidelines section of this policy ○ Requests for a daily dose above 450 mg will be subject to the off-label quantity limit criteria listed in the policy guidelines section of this policy 	
BLOOD GLUCOSE REGULATORS	
Drug	Quantity Limit per 30 days
Baqsimi	2 units; a one-time override may be granted, however, in the case that a member needs an extra kit to be kept in more than 2 locations at one time (i.e., home, school, bus, daycare center)
GlucaGen 1 mg HypoKit	
Glucagon 1 mg Emergency Kit	
Gvoke Syringe	
Zegalogue Syringe/Autoinjector	
Cequor Simplicity Patch	10 patches per 30 days- quantity limit exceptions will be granted if the patient is using more than 180 units of insulin
Invokana 100 mg, 300 mg tablets	30 tablets; approval of a 200 mg dose (100mg tabs, 60/30 days) will only be approved if Invokana is being prescribed for patients using a chronic UGT enzyme inducer (e.g., phenytoin, phenobarbital, ritonavir) concomitantly.
DERMATOLOGICAL AGENTS	
Drug	Quantity Limit per 30 days
Santyl Ointment	180 grams per 30 days - quantities over this amount will be verified for appropriateness using a standard dosing calculator that determines quantity needed based on wound width, length, and duration of therapy. Reference: Santyl dosing calculator
CARDIOVASCULAR AGENTS	
Drug	Quantity Limit per 30 days
Nymalize 60 mg/10 mL solution	1 bottle (237 mL) - approval of an additional quantity will be based on the number of doses needed to complete a 21-day course. The quantity approved may be rounded up to the nearest whole bottle.
Nymalize 30 mg/ 5mL oral syringe	120 mL (24 syringes) - approval of an additional quantity will be based on the number of doses needed to complete a 21-day course
Nymalize 60 mg/10 mL oral syringe	240 mL (24 syringes) - approval of an additional quantity will be based on the number of doses needed to complete a 21-day course
Xarelto 1 mg/mL Oral Suspension	<p>310 mL (2 bottles) per 30 days</p> <p>An additional 310 mL, for a total of 620 mL (4 bottles) per 30 days, may be approved for patients less than 18 years of age who are unable to swallow whole tablets</p> <p>a. For adult patients unable to swallow tablets, Xarelto tablets may be crushed and mixed with applesauce immediately prior to use and administered orally. Additionally, Xarelto tablets may be crushed and suspended in 50 mL of water and administered via an NG tube or gastric feeding tube. Please see the package insert for additional information.</p>
Drug	Quantity Limit per 30 days
Vascepa 0.5 GM	<p>120 capsules/30 days</p> <p>A quantity exception may be granted to obtain a daily dose of 4 grams if the patient had serious side effects or drug failure with Vascepa 1 GM capsules or Icosapent Ethyl 1 GM capsules at a daily dose of 4 grams.</p>

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Icosapent Ethyl 0.5 GM	120 capsules/30 days A quantity exception may be granted to obtain a daily dose of 4 grams if the patient had serious side effects or drug failure with Icosapent Ethyl 1 GM capsules at a daily dose of 4 grams.
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COVID-19 AT HOME TEST KITS – Safety Net Formularies

Test Name*	NDC	Quantity Limit
BinaxNOW COVID-19 Antigen Self- Test	11877-0011-40	Quantity Limit is formulary specific Child Health Plus/Essential Plan: 4 tests per 7 days
QuickVue At-Home COVID-19 Test	14613-0339-72	
InteliSwab COVID-19 Rapid Test	08337-0001-58	
CareStart COVID-19 Antigen Home Test	50010-0224-31	
iHealth COVID-19 Antigen Home Test	56362-0005-89	
Flowflex COVID-19 Antigen Home Test	82607-0660-26	
Flowflex COVID-19 Antigen Home Test	82607-0660-27	
Clinitest COVID-19 Antigen Home Test	16490-0025-73	
On-Go COVID-19 Antigen Home Test	60007-0930-40	
Indicaid COVID-19 Antigen Home Test	60008-0407-80	
Genabio COVID-19 Antigen Home Test	96852-0254-31	

*Covered at home test kits for Child Health Plus and Essential Plan formularies

GENITOURINARY AGENTS

Drug	Quantity Limit per 30 days
Caverject	6 injections
Cialis 10 mg, 20 mg	6 tablets
Edex	6 injections
Levitra, Vardenafil	6 tablets
Muse	6 pellets
Sildenafil 25 mg, 50 mg, 100 mg	6 tablets
Stendra	6 tablets
Staxyn, Vardenafil ODT	6 tablets
Tadalafil 10 mg, 20 mg	6 tablets
Viagra 25 mg, 50 mg, 100 mg	6 tablets

A quantity exception will be authorized for brand/generic Viagra, Cialis, and Levitra when being used for penile rehab after radical prostatectomy. Once daily dosing will be allowed for up to 36 weeks (252 days) of continuous daily use and must be prescribed by a urologist or oncologist. Initiation of therapy may begin up to two weeks before or within 1 year following radical prostatectomy. Requests beyond one year of radical prostatectomy will not be approved.

HORMONAL AGENTS, STIMULANT/REPLACEMENT/MODIFYING (SEX HORMONES/MODIFIERS)

A quantity exception for hormonal agents (sex hormones/modifiers) will be authorized for a diagnosis of gender dysphoria.

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OPHTHALMIC AGENTS		
Drug	Quantity Limit per 30 days	
Eysuvis 0.25%	<p>8.3 mL (1 bottle)</p> <p><u>An exception to this limit must meet the following criteria:</u></p> <ol style="list-style-type: none"> Some patients using the maximum recommended daily dose (two drops in each eye 4 times a day; total of 16 drops per day) may need a second bottle to complete a 14-day treatment course as one bottle, at the maximum daily dose, will last 10 days OR According to the prescribing information, Eysuvis should only be renewed after examination under magnification such as a slit lamp and evaluation of the intraocular pressure; therefore, provider attestation that the patient has been evaluated as such will be required if an additional course of treatment is needed within the same 30-day period 	
RESPIRATORY TRACT/PULMONARY AGENTS		
Drug	Quantity Limitation	
Adrenaclick 0.15 mg auto-injector	<p>These products are limited to 2 units (1 twin pack) per day, and a maximum of 6 units (3 twin packs) per 30 days. A quantity override may be considered in cases where a member needs an additional supply based on medical necessity (where additional doses or storage at additional locations are required)</p>	
Adrenaclick 0.3 mg auto-injector		
Auvi-Q 0.3 mg auto-injector		
Auvi-Q 0.15 mg auto-injector		
Auvi-Q 0.1 mg auto-injector		
Epinephrine 0.15 mg auto-injector		
Epinephrine 0.3 mg auto-injector		
Epipen 2-Pak 0.3 mg auto-injector		
Epipen Jr. 2-Pak 0.15 mg auto-injector		
Symjepi 0.15 mg prefilled syringe		
Symjepi 0.3 mg prefilled syringe		
Drug	Quantity Limitation	
Airsupra 90 mcg-80 mcg inhaler	<p>These products are limited to 1 inhaler per day, and a maximum of 2 inhalers per 30 days. A quantity override may be considered in cases where a member needs an additional supply for storage at additional locations (daycare, school, etc.)</p>	
Breyna 80 mcg-4.5 mcg inhaler		
Breyna 160 mcg-4.5 mcg inhaler		
budesonide/formoterol 80 mcg-4.5 mcg inhaler		
budesonide/formoterol 160 mcg-4.5 mcg inhaler		
Symbicort 80 mcg-4.5 mcg inhaler		
Symbicort 160 mcg-4.5 mcg inhaler		
SLEEP DISORDER AGENTS		
Drug	Generic Counterpart	Quantity Limitation
Lunesta	Eszopiclone	<p>All these medications are limited to once nightly dosing. Based on recent safety data regarding some of the medications, exceptions for a dose above the maximum recommended FDA limit will not be authorized.</p>
Rozerem	Ramelteon	
Sonata	Zaleplon	

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MISCELLANEOUS THERAPEUTIC AGENTS	
Drug	Quantity Limitation
Methergine	<p style="text-align: center;">28 tablets for 7 days</p> <p><u>An exception to this limit must meet the following criteria:</u></p> <ol style="list-style-type: none"> 1. Diagnosis of refractory chronic migraine headache AND 2. A reasonable trial resulting in therapeutic failure or severe intolerance from THREE different classes of the following treatments: (Example: 2 Beta Blockers and 1 Calcium Channel Blocker would NOT meet criteria, but a Beta Blocker, Calcium Channel Blocker and Anticonvulsant would meet criteria) <ul style="list-style-type: none"> ▪ Beta Blockers ▪ Calcium Channel Blockers ▪ Tricyclic Antidepressants ▪ Anticonvulsants AND
Methylergonovine	<ol style="list-style-type: none"> 3. A reasonable trial resulting in therapeutic failure or severe intolerance of Botox (onabotulinumtoxinA injection) AND 4. A reasonable trial resulting in therapeutic failure or severe intolerance with Aimovig (erenumab-aooe injection) 5. Approval quantity for this indication will be limited to a maximum of 240 tablets per 30 days 6. Approval period will be limited to 6 months 7. Continuation of therapy greater than 6 months requires a 1-month drug holiday and a new approval
Tramadol 25 mg	<p style="text-align: center;">120 capsules/365 days</p> <p>A quantity exception may be granted to allow for adequate dose titration</p>

POLICY GUIDELINES:

1. For drugs that do not have specified criteria, all requests above the imposed quantity limit will be evaluated based on FDA-approved dosing for the corresponding FDA-approved indication, length of therapy, body surface area (BSA), compendia listing, and/or primary literature supporting the request.
 - a. For off-label non-cancer quantity requests, the requested use (including both dosage and diagnosis) must be listed in DrugDex as recommendation class IIa or higher. If the requested use (including both dosage and diagnosis) is listed as IIb or is not listed, then there must be published clinical research that meets all the following criteria:
 - i. At least one phase III clinical trial that definitively demonstrates safety and effectiveness of the use of the requested drug
 - 1) The trial must be published in national or international peer-reviewed (editorial committee is comprised of physicians) journal. This excludes case reports, letters, posters, and abstracts
 - 2) The trial must establish appropriate dose and dosing frequency (approvals will be limited to the dosing regimen established in the literature)
 - 3) In determining whether the clinical trial is definitively supportive, the following will be assessed:
 - a) The prevalence of the disease and subject size sufficient to determine statistical validity
 - b) Whether the clinical characteristics of the patient and the indication are adequately represented in the published evidence

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- c) The effect on the individual's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, and signs and symptoms)
 - d) Whether the study outcomes represent clinically meaningful outcomes experienced by patients
 - e) Appropriateness of study design (accepted study design: randomized, double blind, placebo controlled clinical trial)
 - b. For off-label quantity requests for the treatment of cancer, the requested dose must be listed in DrugDex as recommendation class IIa or higher. If the use is listed as IIb or is not listed, then consult NCCN Drugs and Biologics Compendium. The requested dose must have a category I or IIa recommendation to be considered medically acceptable. If the requested dose is not listed or is listed as category IIb, then consult AHFS and/or Clinical Pharmacology. The requested dose must have a supportive narrative to be considered medically acceptable. If the requested dose is not listed or supported, then there must be at least 1 published article in a peer reviewed journal. The study must include a sufficient number of subjects demonstrating that the use of the drug at the requested dose is generally safe and results in clinically meaningful outcomes at a level that is superior to standard FDA dosing.
2. Quantity limits are imposed on both existing and new to the market drugs. The most up to date quantity limit list can be found on our website or requested from the Pharmacy Management Helpdesk.
3. Dose efficiency can apply to any medication that has a quantity limit imposed on it. An override of the dose efficiency edit for multiple lower strength doses will only be authorized if the patient has had serious side effects or drug failure to at least a 2-week trial of a higher strength, similar dose, formulation. For example, we would require Vesicare 10 mg one tablet daily prior to Vesicare 5 mg two tablets daily.
4. Standard approval time is one year. Exceptions to the standard approval time frame include:
 - a. Instances where dose titration (up or down) is occurring, the approval period may be shortened.
 - b. Off-label quantity requests – the approval time frame for off-label quantity requests will be for up to 6 months and will depend on expected period to determine safety and efficacy of the drug. Approval time frame will be individualized based on case-specific factors and may vary.
5. Recertification: Medication compliance is required for those members who have been granted a quantity exception. Patients with a medication history profile demonstrating repeated fills less frequently than what has been requested (or the days' supply being submitted) will be denied further authorization of a quantity override. In addition, recertification of off-label quantity requests will require documentation that the drug, given at the quantity requested that is outside of FDA approved dosing, is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the product at the requested quantity limit is medically necessary.
6. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
7. Clinical Review criteria related to gender dysphoria has been reviewed and approved by the New York State Office of Mental Health.
8. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required.
 - a. The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
 - b. The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;

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- c. The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
- d. The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
- e. The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rationale for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
- f. The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.

UPDATES:

Date	Revision
03/20/2024	Revised
02/8/2024	Revised
12/06/2023	Revised
11/30/2023	P&T Committee Approval
09/11/2023	Revised
08/03/2023	Revised
05/12/2023	Revised
04/01/2023	Revised
12/2022	Revised
11/2022	Revised / P&T Committee Approval
07/2022	P&T Committee Approval
06/2022	Revised
05/2022	Revised
03/2022	Revised
01/2022	Revised
12/2021	Revised
11/2021	Revised
10/2021	Revised
08/2021	Revised
07/2021	Reviewed / P&T Committee Approval
07/2021	Revised
05/2021	Revised
04/2021	Revised
12/2020	Revised
09/2020	Reviewed / P&T Committee Approval
05/2020	Revised
02/2020	Revised
10/2019	Revised
08/2019	Revised
07/2019	Revised
03/2019	Revised
02/2019	P&T Committee Approval
11/2018	Revised

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10/2018	Revised
07/2018	Revised
06/2018	Revised
04/2018	Revised
01/2018	Revised
11/2017	Revised
10/2017	Revised
05/2017	P&T Committee Approval
04/2017	Revised
05/2016	Revised
10/2015	Revised
09/2015	Revised
06/2015	Revised
12/2014	Revised
09/2014	Revised
04/2014	Revised
09/2013	Revised
07/2012	Revised