Pharmacy Management Drug Policy

SUBJECT: Quantity Limit
POLICY NUMBER: PHARMACY-43
EFFECTIVE DATE: 01/2000
LAST REVIEW DATE: 10/01/2024

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:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ 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.

ANTICONVULSANTS	
Drug	**Quantity Limitation**
Nayzilam	Covered for a maximum of 5 packages per 30 days • 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: • 500mg tablet: 20 tablets per 30 days • 100mg/5ml suspension: 150ml per 30 days Exception: 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
Elyxyb 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:
- 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)

*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

BEHAVIORAL HEALTH

Drug	Quantity Limit per 30 days
Wellbutrin XL 150 mg tablet	30 tablets

A quantity exception may be granted to obtain a daily dose of 450 mg if the following criteria is met:
- Must have had serious side effects or drug failure of bupropion XL 150 mg **AND** bupropion XL 450 mg
  - 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	
Cequr 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**
Entresto 24 mg/26 mg	60 tablets/30 days; for pediatric patients weighing at least 40 kg, a quantity limit exception may be granted to allow for 180 tablets per 30 days, to achieve titration/final dose of 72 mg/78 mg twice daily.
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	**310 mL (2 bottles) per 30 days** 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 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.
Drug	**Quantity Limit per 30 days**
Vascepa 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 Vascepa 1 GM capsules or Icosapent Ethyl 1 GM capsules at a daily dose of 4 grams.
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.

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.

OPHTHALMIC AGENTS	
Drug	**Quantity Limit per 30 days**
Eysuvis 0.25%	**8.3 mL (1 bottle)** An exception to this limit must meet the following criteria: 1. 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** 2. 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	These products are limited to 2 units (1 twin pack or 1 carton of Neffy) per day, and a maximum of 6 units (3 twin packs or 3 cartons of Neffy) 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)
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	
Neffy 2 mg/0.1 mL nasal spray	
Symjepi 0.15 mg prefilled syringe	
Symjepi 0.3 mg prefilled syringe	
Drug	**Quantity Limitation**
Airsupra 90 mcg-80 mcg inhaler	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.)
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	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.
Rozerem	Ramelteon	
Sonata	Zaleplon	

MISCELLANEOUS THERAPEUTIC AGENTS

Drug	Quantity Limitation
Methergine	**28 tablets for 7 days** <u>An exception to this limit must meet the following criteria</u>: 1. Diagnosis of refractory chronic migraine headache **AND** 2. A reasonable trial resulting in therapeutic failure or severe intolerance from **<u>THREE</u>** different classes of the following treatments: (Example: 2 Beta Blockers and 1 Calcium Channel Blocker would **<u>NOT</u>** meet criteria, but a Beta Blocker, Calcium Channel Blocker and Anticonvulsant would meet criteria) ▪ Beta Blockers ▪ Calcium Channel Blockers ▪ Tricyclic Antidepressants ▪ Anticonvulsants **AND** 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
Methylergonovine	
Tramadol 25 mg	**120 capsules/365 days** A quantity exception may be granted to allow for adequate dose titration

VACCINES

Drug	Quantity Limitation
Abrysvo	Based on current Centers for Disease Control and Prevention (CDC) / Advisory Committee on Immunization Practices (ACIP) guidance, Abrysvo, Arexvy, and mResvia will be limited to one dose per lifetime per patient.
Arexvy	
mResvia	

<u>POLICY GUIDELINES</u>:

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
   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. For example, we would require Vesicare 10 mg one tablet daily prior to Vesicare 5 mg two tablets daily. An override of the dose efficiency edit for multiple lower strength doses will only be authorized if the patient has experienced one of the following (documentation must be provided):
   a. An inability to tolerate the requested dose in the most dose efficient manner
   b. Drug failure to at least a 4-week trial of a higher strength, similar dose, formulation.
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.
6. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, imaging and other objective or subjective measures of benefit which support continued use of the product at the requested quantity limit is medically necessary.
7. 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.

8. Clinical Review criteria related to gender dysphoria has been reviewed and approved by the New York State Office of Mental Health.
9. 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;
   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 rational 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:

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