Pharmacy Management Drug Policy

SUBJECT: Quantity Limit Policy
POLICY NUMBER: PHARMACY- 43
EFFECTIVE DATE: 1/00
LAST REVIEW DATE: 2/5/2020

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. Medical or drug policies apply to commercial, SafetyNet, and Health Care Reform products only when a contract benefit for the specific service exists.

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	Covered for a maximum of 180 days of continuous therapy within a rolling 12-month period **(This does not apply to Managed Medicaid)**
Evzio	2 auto-injectors (one carton) per 30 days. A quantity exception may be requested by the prescriber and will be reviewed based on appropriate documentation supporting medical necessity.

ANTICONVULSANTS	
Drug	**Quantity Limitation**
Nayzilam	Covered for a maximum of 5 dosage units per 30 days – FDA labeling recommends that diazepam rectal gel be used to treat no more than 5 episodes per month and no more than 1 episode every 5 days for Diastat/Diazepam and every 3 days for Nayzilam.
Diastat, Diazepam Rectal Gel	
Valtoco	

ANTICOAGULANTS

Drug	Quantity Limitation
Bevyxxa	43 tablets per 42 days within a rolling 365-day period. A quantity exception may be requested by the prescriber and will be reviewed based upon appropriate documentation supporting medical necessity.

ANTIMIGRAINE AGENTS

Drug	Generic Counterpart	Quantity Limits per # of days	
Amerge	Naratriptan	18 tablets	28
Axert	Almotriptan	12 tablets	28
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
Sumavel Dosepro		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		12 sprays	30
Cambia 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)

CENTRAL NERVOUS SYSTEM AGENTS

Drug	Quantity Limit
Tiglutik 50mg/10mL Susp	A quantity of 600 mL per 30 days is allowed for a diagnosis of Amyotrophic Lateral Sclerosis (ALS). A quantity of 1200 mL per 30 days will only be approved for a diagnosis of Chorea of Huntington's disease.

BLOOD GLUCOSE REGULATORS	
Drug	**Quantity Limit per 30 days**
Gvoke Syringe Glucagon 1 mg emergency kit 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)
Diabetic Blood Glucose Test Strips	**<u>These criteria apply to Medicaid Managed Care (MMC) members only:</u>** ▪ Individuals NOT receiving insulin therapy are limited to a maximum quantity of 102 test strips per 30 days ▪ Individuals currently receiving insulin therapy are limited to a maximum quantity of 306 test strips per 30 days ▪ Quantity exceptions can be requested by the provider and will be reviewed based on appropriate documentation supporting medical necessity

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. <u>Reference: Santyl dosing calculator</u>

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 Viagra, Cialis, and Levitra when being used for penile rehab after radical prostatectomy. Once daily dosing of either medication will be allowed for up to 36 weeks (252 days) of continuous daily use and must be prescribed by a urologist or oncologist.	

Drug	**Quantity Limit**
Thiola 100 mg	10 tablets
Thiola EC 100 mg	10 tablets
Thiola EC 300 mg	3 tablets
<u>Please Note:</u> Initial dosing is 800 mg per day. A multi-clinic trial demonstrated an average dose of approximately 1,000 mg/day. Dosage can be adjusted depending on urinary cystine levels. **<u>Exceptions</u>** to the quantity limit can be made when there is documentation of conservative therapy in combination with standard dosing of Thiola. <u>Conservative treatment includes:</u> Intake of at least 3 L of fluid (ten 10 oz. glassfuls), including 2 glasses with each meal and at bedtime. The patients should be expected to awake at night to urinate; they should drink 2 more glasses of fluids before returning to bed. Additional fluids should be consumed if there is excessive sweating or intestinal fluid loss. A minimum urine output of 2 L/day on a consistent basis should	

be sought. A modest amount of alkali should be provided in order to maintain urinary pH at a high normal range (6.5 to 7).

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.

RESPIRATORY TRACT/PULMONARY AGENTS

Drug	Quantity Limitation
Auvi-Q 0.3 mg auto-injector	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)
Auvi-Q Jr. 0.15 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	

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** An exception to this limit must meet the following criteria: 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) ▪ 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	

Policy Guidelines:

1. For drugs that do not have specified criteria, requests will be evaluated based on FDA labeling, compendia listing or primary literature supporting the request. The use must be listed in DrugDex as recommendation class IIa or higher. If the use is listed as IIb or is not listed, then there must be 1 published article or 2 published abstracts with 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 FLRx 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 therapeutic failure, or severe intolerance to at least a 2-week trial of the equivalent higher strength 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. In instances where dose titration (up or down) is occurring, the approval period may be shortened.

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.

6. 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:

Date	Revision
2/20	Revised
10/19	Revised
8/19	Revised
7/19	Revised
3/19	Revised
2/19	Committee Approval
11/18	Revised
10/18	Revised
7/18	Revised
6/18	Revised
4/18	Revised
1/18	Revised
11/17	Revised
10/17	Revised
5/17	Committee Approval
4/17	Revised
5/16	Revised
10/15	Revised
9/15	Revised
6/15	Revised
12/14	Revised
9/14	Revised
4/14	Revised
9/13	Revised
7/12	Revised