

Pharmacy Policy Bulletin

Title: Quantity Level Limits for Pharmaceuticals Covered Under the Pharmacy Benefit

Policy #: Rx.01.76

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▶ Intent:

Applicable medications may not be appropriate for members when prescribed in quantities above quantity level limits. Quantities exceeding the quantity level limits may create safety concerns or inappropriate utilization issues. Medications subject to quantity level limits are reviewed by the Pharmacy and Therapeutics (P&T) Committee.

▶ Description:

Quantity limits are designed to allow a sufficient supply of medication based upon FDA-approved or medically accepted maximum daily doses and length of therapy of a particular drug. Quantity limits may be expressed as quantity over time or maximum daily dose. Additionally, there are some medications to which a limit on the days' supply is applied.

1. Quantity over time: This quantity limit is based on dosing guidelines over a rolling time period, usually 30 days.
2. Maximum daily dose (maximum quantity per day): This quantity limit is based on maximum number of units of the drug allowed per day. Maximum daily dose supersedes quantity over time.
3. Days' supply limit: This limits the numbers of days of therapy in a defined time period. Maximum daily dose applies to days' supply limits.

Refer to the specific manufacturer's prescribing information for additional details.

Quantity limits for opioids are included in the opioid management policy.

▶ Policy:

General quantity limit criteria

Criteria for exceptions above the quantity limit (drug specific criteria below).

1. For requests that exceed the FDA approved maximum dose: A quantity limit exceeding those listed in the following table is approved when there is documentation of a randomized, double blind, active or placebo controlled trial demonstrating the safety and efficacy of the

- requested dose for the indication, where the results are published in a national peer-reviewed journal.
2. For requests that do not exceed the FDA approved maximum dose: A quantity limit exceeding those listed in the following table is approved when there is documentation of the inability to reach the requested dose with commercially available dosage forms.
 3. For requests that do not have the FDA approved maximum dose: A quantity limit exceeding those listed in the following table is approved when there is documentation of medical necessity.

Drug specific quantity limit criteria

Icatibant (Firazyr®) specific criteria:

A quantity limit exceeding those listed is approved when BOTH of the following criteria are met:

1. The total dose does not exceed FDA approved maximum dose
2. ONE of the following:
 - a. For Hereditary Angioedema (HAE) Types I and II: documentation of an inadequate response or inability to tolerate C1 inhibitor replacement therapy (e.g., Cinryze, Berinert); or
 - b. For HAE non-Type I or II: documentation of medical necessity

Migraine Agents specific criteria:

An increased quantity of a migraine agent is approved when there is a diagnosis of migraine headache and all of the following inclusion criteria are met:

1. Trial of prophylactic treatment with one of the following: beta blocker, calcium channel blocker, tricyclic antidepressant, valproic acid, cyproheptadine or topiramate; and
2. Requested quantity does not exceed the manufacturer-recommended maximum doses; and
3. The individual has been examined by a neurologist within the past three years.

Proton pump inhibitor specific criteria:

Increased quantity limits of proton pump inhibitors are approved when ONE of the following is met:

1. Pathological hypersecretory condition including Zollinger-Ellison syndrome; or
2. Barrett's esophagus; or
3. Upper gastrointestinal bleed (gastric or duodenal); or
4. Failure of once daily proton pump inhibitor therapy with ONE of the following:
 - a. Gastroesophageal reflux disease (GERD) with nocturnal symptoms
 - b. GERD or erosive esophagitis for member less than 11 years old
 - c. Laryngopharyngeal reflux
 - d. Treatment for the eradication of H pylori with triple therapy (duration of therapy will be limited to 14 days)

Smoking Cessation Agents specific criteria:

Additional days' supply of bupropion (Zyban), Varenicline (Chantix) and Nicotine Replacements (Nicotine gum, patches, inhalers, and spray) are approved when all the following are met:

1. One month has passed since last failure
2. Member is enrolled in a Smoking Cessation Program (in person or online)
3. Member is currently a smoker

Authorization length: 6 months

Epinephrine pens/ auto-injectors

A quantity limit exceeding those listed may be considered with documentation that a member needs an additional supply based on medical necessity (where additional doses or storage at additional locations are required).

Authorization length: 6 months



Black Box Warning:

Refer to the specific manufacturer's prescribing information for details.



Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.



References:

Micromedex. Available at <http://www.micromedexsolutions.com/>. Accessed June 24, 2017.



Applicable Drugs:



Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Medication	Maximum Quantity per day	Quantity limit per rolling 30 days, unless otherwise specified (tablets, capsules, mL)
ADHD Agents		
Dextroamphetamine/Amphetamine (Adderall) 5mg, 7.5mg, 10mg, 12.5mg, 15mg and 20mg	3	90
Dextroamphetamine/Amphetamine (Adderall) 30mg	2	60
Dextroamphetamine/Amphetamine (Adderall XR) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg	1	30
Dextroamphetamine/Amphetamine (Dyanavel XR) 2.5mg/ml Susp	8mL	240
Atomoxetine HCL (Strattera) 10mg, 18mg, 25mg, 40mg	2	60
Atomoxetine HCL (Strattera) 60mg, 80mg, 100mg	1	30
Clonidine HCL (Kapvay) 0.1mg	4	120
Dextroamphetamine sulfate (Dexedrine) 5mg cap SA	3	90

Dextroamphetamine sulfate (Dexedrine) 10mg cap SA	6	180
Dextroamphetamine sulfate (Dexedrine) 15mg cap SA	4	120
Dextroamphetamine sulfate 5mg tablet	3	90
Dextroamphetamine sulfate 10mg tablet	3	90
Dexmethylphenidate HCL (Focalin) 2.5mg, 5mg, 10mg	2	60
Dexmethylphenidate HCL (Focalin XR) 5mg, 10mg, 15mg, 20mg, 25mg, 30mg, 35mg, 40mg	1	30
Dextroamphetamine sulfate (Procentra) 5mg/5ml solution	60	1800
Dextroamphetamine (Zenzedi) 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg tablet	3	90
Dextroamphetamine (Zenzedi) 30mg tablet	2	60
Guanfacine HCL (Intuniv ER) 1mg, 2mg, 3mg, 4mg tablet	1	30
Lisdexamfetamine dimesylate (Vyvanse) 20mg, 30mg, 40mg, 50mg, 60mg, 70mg	1	30
Methylphenidate HCL (Concerta) 18mg, 27mg, 54mg	1	30
Methylphenidate HCL (Concerta) 36mg tablet ER	2	60
Methylphenidate (Daytrana patch) 10mg/9hr, 15mg/9hr, 20mg/9hr, 30mg/9hr	1	30
Methamphetamine HCL (Desoxyn) 5mg tablet	5	150
Methylphenidate HCL (Metadate CD) 10mg, 20mg, 30mg, 40mg, 50mg, 60mg	1	30
Methylphenidate HCL (Metadate ER) 10mg, 20mg tablet SA	3	90
Methylphenidate HCL (Methylin) 2.5mg, 10mg chewable tablet	6	180
Methylphenidate HCL (Methylin) 5mg chewable tablet	3	90
Methylphenidate HCL (Methylin) 10mg/5ml	30	900
Methylphenidate HCL (Methylin) 5mg/5ml	60	1800
Methylphenidate HCL (Ritalin) 5mg, 10mg, 20mg	3	90
Methylphenidate HCL (Ritalin LA) 10mg, 40mg capsule	1	30
Methylphenidate HCL (Ritalin LA) 20mg capsule	3	90
Methylphenidate HCL (Ritalin LA) 30mg capsule	2	60
Antiemetics		
Aprepitant (Emend) 80mg	NA	8
Aprepitant (Emend) 40mg	NA	2
Aprepitant (Emend) 125mg	NA	4
Aprepitant (Emend) trifold pack	NA	4 packs
Antidepressant		
Fluoxetine (Prozac weekly)	NA	4

Antivirals/Anti-infectives		
Fidaxomicin (Dificid)	NA	20/10 days
Isavuconazonium (Cresemba) capsule	NA	68
Oseltamivir (Tamiflu) 6mg/ml	NA	180mL (3 bottles) per Rx
Oseltamivir (Tamiflu) 30mg	NA	20 perRx
Oseltamivir (Tamiflu) 45mg, 75mg	NA	10 perRx
Posaconazole (Noxafil) 100mg tab	NA	93
Tedizolid phosphate (Sivextro)	NA	6 per 6 days
Penciclovir (Denavir)	NA	5 grams
Zanamivir (Relenza)	NA	1 Diskhaler per Rx
Acyclovir cream (Zovirax)	NA	5g
Acyclovir ointment (Zovirax)	NA	30g
Contraceptives		
Diaphragm	NA	1 per year
Ethinyl estradiol/etonogestrel (Nuvaring)	NA	1per 28 days
Ethinyl estradiol/norelgestromine (Ortho Evra, Xulane patch)	NA	3
Female condoms	NA	15
Levonorgestrel 1.5mg (My Way, Next Choice, One Dose, Plan B one-step)	NA	3
Medroxyprogesterone acetate (Depo-Provera)	NA	1 per 90 days
Ulipristal (Ella)	NA	3
Diabetic Supplies		
Blood glucose monitor	NA	2 per year
Diabetic test strips	NA	200
Insulin injecting device (e.g. Novopen)	NA	2per year
Insulin syringes and pen needles	NA	200
Lancets	NA	200
Erectile Dysfunction		
Alprostadil (Caverject)	NA	8
Alprostadil (Edex, Muse)	NA	8
Avanafil (Stendra)	NA	8
Sildenafil (Viagra)	NA	8
Tadalafil (Cialis) 2.5mg, 5mg	1	30
Tadalafil (Cialis) 10mg, 20mg	NA	8
Vardenafil (Levitra, Staxyn)	NA	8
Injectable Fertility		
Urofollitropin (Bravelle) 75 unit vial	NA	60
Follitropin Beta (Follistim AQ) 75 unit vial	NA	60
Follitropin Beta (Follistim AQ) 150 unit vial	NA	30
Follitropin Beta (Follistim AQ) 300 unit cartridge	NA	15
Follitropin Beta (Follistim AQ) 600 unit cartridge	NA	8
Follitropin Beta (Follistim AQ) 900 unit cartridge	NA	5
Follitropin Alfa (Gonal-F) 450 units vial	NA	10
Follitropin Alfa (Gonal-F) 1050 units vial	NA	5
Follitropin Alfa (Gonal-F RFF) 300/0.5ml pen injector	NA	15

Follitropin Alfa (Gonal-F RFF) 450/0.75ml pen injector	NA	10
Follitropin Alfa (Gonal-F RFF) 900/1.5ml pen injector	NA	5
Follitropin Alfa (Gonal-F RFF) 75 unit vial	NA	60
Menotropins (Menopur, Repronex) 75 units vial	NA	60
Migraine Agents		
Almotriptan (Axert) 6.25mg	NA	12
Almotriptan (Axert) 12.5mg	NA	12
Eletriptan (Relpax) 20mg, 40mg	NA	12
Butorphanol nasal spray	NA	10
Dihydroergotamine (Migranal)	NA	8
Frovatriptan (Frova) 2.5mg	NA	18
Naratriptan (Amerge) 1mg, 2.5mg	NA	9
Rizatriptan (Maxalt and Maxalt MLT) 5mg and 10mg	NA	12
Sumatriptan (Imitrex) 4mg injections	NA	14 kits (28 injections)
Sumatriptan (Imitrex) 6mg injections	NA	9 kits (18 injections)
Sumatriptan (Imitrex) 5mg/actuation nasal spray	NA	36
Sumatriptan (Imitrex) 20mg/actuation nasal spray	NA	18
Sumatriptan (Imitrex) 6mg/0.5ml subcutaneous cartridge/pen injection	NA	9ml
Sumatriptan (Imitrex) 4mg/0.5ml subcutaneous cartridge/pen injection	NA	14ml
Sumatriptan (Imitrex) 25mg, 50mg, 100mg	NA	18
Sumatriptan (Sumavel)	NA	9ml
Sumatriptan/Naproxen (Treximet) 85mg/500mg	NA	18
Zolmitriptan (Zomig, Zomig ZMT) 2.5mg, 5mg	NA	9
Zolmitriptan (Zomig) 2.5mg, 5mg nasal spray	NA	9
Miscellaneous		
Cyclosporine (Restasis)	2	60
Diclofenac (Flector) patch	2	60
Diclofenac potassium (Zipsor)	4	120
Diclofenac sodium (Conzip)	1	30
Epinephrine pens/ auto-injectors (Epi-Pen, Adrenaclick, Auvi-Q)	NA	3 twin packs (6 injections) per 180 days
Icatibant (Firazyr 30mg/3ml syringe)	NA	27mL
Ketorolac tromethamine (Sprix)	NA	5
Lidocaine (Lidoderm) patch	3	90
Naloxone (Evzio)	NA	4
Sacubitril/valsartan (Entresto)	2	60
Sodium oxybate (Xyrem)	18	540
Multiple sclerosis agents		
Dalfampridine (Ampyra)	2	60
Interferon beta-1a (Avonex)	NA	4
Interferon beta-1a (Rebif/Rebif Rebidose)	NA	12
Interferon beta-1b (Betaseron)	NA	15

Interferon beta-1b (Extavia)	NA	15	
Glatiramer acetate (Copaxone 20mg)	1	30	
Glatiramer acetate (Copaxone 40mg)	NA	12	
Peginterferon beta-1a (Plegridy)	NA	1mL per 28 days	
Osteoporosis Agents			
Alendronate 70mg/75ml solution	NA	300mL per 28 days	
Alendronate (Fosamax and Binosto) 35mg, 70mg	NA	4 per 28 days	
Alendronate with Vitamin D (Fosamax plus D) 70mg/2.8ml, 70mg/5.6ml	NA	4 per28 days	
Ibandronate (Boniva) 150mg	NA	1	
Risedronate sodium (Actonel and Atelvia) 35mg	NA	4 per28 days	
Risedronate sodium (Actonel) 150mg	NA	1 per30 days	
Proton Pump Inhibitor			
Dexlansoprazole (Dexilant)	2	60	
Esomeprazole magnesium (Nexium) and strontium capsules	2	60	
Esomeprazole magnesium (Nexium) packet	1	30	
Lansoprazole (Prevacid)	2	60	
Lansoprazole (Prevacid) solu-tab	1	30	
Omeprazole (Prilosec)	2	60	
Omeprazole/sodium bicarbonate (Zegerid) packets	1	30	
Pantoprazole sodium (Protonix)	2	60	
Pantoprazole sodium (Protonix) packet	1	30	
Rabeprazole (Aciphex)	2	60	
Rabeprazole (Aciphex) sprinkle	1	30	
Sedative Hypnotics			
Estazolam	1	30	
Eszopiclone (Lunesta) 1mg	2	60	
Eszopiclone (Lunesta) 2mg, 3mg	1	30	
Flurazepam HCL	1	30	
Ramelteon (Rozerem)	1	30	
Suvorexant (Belsomra)	1	30	
Tasimelteon (Hetlioz)	1	30	
Temazepam (Restoril)	1	30	
Triazolam (Halcion)	1	30	
Zaleplon (Sonata)	1	30	
Zolpidem (Zolpimist)	NA	7.7ml (1 pump)	
Zolpidem tartrate (Ambien, Ambien CR, Edluar, Intermezzo)	1	30	
Smoking Cessation Products			
Bupropion HCL (Zyban)	2	60	180 cumulative days' supply per 365 days
Nicotine gum/inhaler/lozenges	10	300	
Nicotine patches	1	30	
Varenicline (Chantix)	2	60	



Cross References:

Attention Deficit Hyperactivity Disorder Agents Rx.01.12

Brand Drugs with Generic Alternatives Rx.01.165
Diclofenac Products Rx.01.155
Epinephrine Pen Policy Rx.01.142
Erectile Dysfunction Agents Rx.01.29
Experimental/ Investigational Policy Rx.01.33
Fertility Agents Rx.01.196
Heart Failure Agents Rx.01.174
Icatibant (Firazyr) Rx.01.109
Migraine Agents Rx.01.56
Multiple Sclerosis Agents Rx.01.122
Naloxone Auto-injector (Evzio) Rx.01.167
Oral Anti-infective Agents Rx.01.66
Proton Pump Inhibitors Rx.01.75
Sleep Agents Rx.01.84
Sodium oxybate (Xyrem) Rx.01.124

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