

## Pharmacy Policy Bulletin

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

**Policy #:** Rx.01.76

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**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, gender or quantity restrictions. 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 and 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:

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

### ↳ Policy:

#### **ADHD agents specific Criteria:**

*For requests that exceed the FDA approved maximum dose*

An increased quantity limit is approved when the following inclusion criterion is met:

- Documentation of a randomized, double blind, active or placebo controlled trial demonstrating the safety and efficacy of the requested dose for the condition submitted, where the results are published in a national peer-reviewed journal.

*For requests that do not exceed the FDA approved maximum dose*

An increased quantity limit is approved when the following inclusion criterion is met:

- Documentation of the inability to reach requested dose with higher strength dosage forms

#### **Proton pump inhibitor specific criteria**

Increased Quantity limits of proton pump inhibitors are approved when one of the following inclusion criteria is met:

- Documentation of one of the following
- Documentation of pathological hypersecretory condition including Zollinger-Ellison syndrome
- Documentation of a diagnosis of Barrett's esophagus
- Documentation of GI bleed
- Documentation of one of the following with failure of once daily proton pump inhibitor therapy
- Diagnosis of gastroesophageal reflux disease (GERD) with nocturnal acid breakthrough
- diagnosis of GERD or erosive esophagitis for a child less than 11 years old
- diagnosis of laryngopharyngeal reflux
  
- Documentation of treatment for the eradication of H pylori with triple therapy (duration of

therapy will be limited to 30 days)

#### ▸ 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:

Actonel® (risendronate) [package insert]. Cincinnati, OH: Proctor & Gamble Pharmaceuticals; 2009. Also available online at: <http://www.actonel.com/prescribinginformation.jsp>. Accessed September 12, 2011.

Avonex® (interferon beta-1a) [package insert]. Cambridge, MA: Biogen Idec Inc.; 2008. Also available online at: [http://www.avonex.com/msavProject/avonex.portal/\\_baseurl/threeColLayout/SCSRepository/en\\_US/avonex/includes/footer/prescribe\\_info\\_med\\_guide.xml](http://www.avonex.com/msavProject/avonex.portal/_baseurl/threeColLayout/SCSRepository/en_US/avonex/includes/footer/prescribe_info_med_guide.xml). Accessed September 12, 2011.

Betaseron® (interferon beta-1b) [package insert]. Montville, NJ: Bayer HealthCare Pharmaceuticals; 2009. Also available online at: [http://www.betaseron.com/prescribing\\_info.jsp](http://www.betaseron.com/prescribing_info.jsp) Accessed September 12, 2011.

Cialis® (tadalafil) [package insert]. Indianapolis, IN: Eli Lilly and Company; February 2010. Also available online at: <http://www.cialis.com>. Accessed September 12, 2011.

Copaxone® (glatiramer acetate) [package insert]. Kansas City, MO: Teva Neuroscience, Inc.; 2009. Available at: <http://www.copaxone.com/pdf/PrescribingInformation.pdf>. Accessed September 12, 2011.

Facts and Comparisons. Sedatives and hypnotics, nonbarbituate monograph. [Facts and Comparisons Web site]. Available at: <http://www.factsandcomparisons.com/efacts.asp> [via subscription only]. (Refer to manufacturers' prescribing information for specific agents). Accessed September 12, 2011.

Product Information: Flector(R) patch topical patch, diclofenac epolamine topical patch, 1.3%. IBSA Institut Biochimique SA, Lugano, Switzerland, 2009. Available at <http://www.flectorpatch.com/pi.cfm>. Accessed September 12, 2011.

Product Information: Lidoderm(R), lidocaine patch 5%. Endo Pharmaceuticals, Chadds Ford, PA, 2010. Available at <http://www.lidoderm.com/prescrib.aspx>. Accessed September 12, 2011.

Fosamax® (alendronate) [package insert]. Whitehouse Station, NJ: Merck & Co., Inc; 2010. Also available online at: [http://www.merck.com/product/usa/pi\\_circulars/f/fosamax/fosamax\\_pi.pdf](http://www.merck.com/product/usa/pi_circulars/f/fosamax/fosamax_pi.pdf). Accessed September 12, 2011.

Rebif® (interferon beta-1a) [package insert]. Rockland, MA: EMD Serono, Inc.; 2008. Also available online at: [http://www.mslifelines.com/\\_assets/pdf/Rebif\\_PI.pdf](http://www.mslifelines.com/_assets/pdf/Rebif_PI.pdf). Accessed September 12, 2011.

Viagra® (sildenafil citrate) [package insert]. New York, NY: Pfizer; 2010. Also available online at: [http://www.pfizer.com/files/products/uspi\\_viagra.pdf](http://www.pfizer.com/files/products/uspi_viagra.pdf). Accessed September 12, 2011.

Dificid [package insert] Optimer Pharmaceuticals Inc. San Diego CA. 2011.

Medication	Quantity Limit (per rolling 30 days unless otherwise noted)
Sedative Hypnotics	
Ambien (zolpidem tartrate)	30 units
Dalmane (flurazepam HCl)	30 units
Doral (quazepam)	30 units
Prosom (estazolam)	30 units
Halcion (triazolam)	30 units
Restoril (temazepam)	30 units
Sonata (zaleplon)	30 units
Zolpimist (zolpidem)	7.7ml (1 pump)
Antivirals	
Relenza	20 units (1 Diskhaler)/Rx
Tamiflu 30 mg	20 capsules/Rx
Tamiflu 45 mg	10 capsules/Rx
Tamiflu 75 mg	10 capsules/Rx
Tamiflu 6mg/ml	180ml(3bottles)/Rx
Tamiflu 12 mg/mL	75 mL/Rx
MS Agents	
Avonex	4 units
Extavia Betaseron	15 units/30 days, 14 units/28 days (determined by product)
Copaxone	30 units
Rebif	12 units
Osteoporosis Agents	
Actonel 35 mg	5 units

Actonel 75mg	2 units/28 days
Actonel 150 mg	2 units/28 days
Fosamax 70 mg	5 units
Fosamax 35 mg	5 units
Fosamax Plus D 70 mg	5 units
Boniva 150 mg	2 units
Erectile Dysfunction Agents	
Caverject	8 units
Cialis 2.5 mg and Cialis 5 mg	30 units
Cialis 10mg and 20mg	8 units
Edex	8 units
Levitra	8 units
MUSE	8 units
Staxyn	8 units
Viagra	8 units
Antiemetics	
Emend	#4 125 mg capsules or
	#8 80 mg capsules or
	#4 tri-fold packs or
	#2 40 mg capsules
Antidepressants	
Prozac weekly	5 units
Miscellaneous	
Lidoderm patch	90 patches
Flector patch	60 patches

Dificid	20 units per 10 days
Sprix	5 bottles
<b>ADHD agents</b>	
Adderall 5 mg tablet (amphet asp/amphet/d-amphet )	90 units
Adderall 7.5 mg tab (amphet asp/amphet/d-amphet)	90 units
Adderall 10 mg tab (amphet asp/amphet/d-amphet)	90 units
Adderall 12.5 mg tab (amphet asp/amphet/d-amphet)	90 units
Adderall 15 mg tab (amphet asp/amphet/d-amphet)	90 units
Adderall 20 mg tab (amphet asp/amphet/d-amphet)	90 units
Adderall 30 mg tab (amphet asp/amphet/d-amphet)	60 units
Adderall XR 5 mg capsule (amphet asp/amphet/d-amphet)	30 units
Adderall XR 10 mg capsule (amphet asp/amphet/d-amphet)	30 units
Adderall XR 15 mg capsule (amphet asp/amphet/d-amphet)	30 units
Adderall XR 20 mg capsule (amphet asp/amphet/d-amphet )	30 units
Adderall XR 25 mg capsule (amphet asp/amphet/d-amphet)	30 units
Adderall XR 30 mg capsule (amphet asp/amphet/d-amphet)	30 units
Concerta 18 mg tablet ER (methylphenidate HCl)	30 units
Concerta 27 mg tablet SA (methylphenidate HCl)	30 units
Concerta 36 mg tablet ER(methylphenidate HCl)	60 units
Concerta 54 mg tablet ER (methylphenidate HCl)	30 units
Daytrana 10 mg/9 hr patch (methylphenidate)	30 units
Daytrana 15 mg/9 hr patch (methylphenidate)	30 units
Daytrana 20 mg/9 hour patch (methylphenidate)	30 units
Daytrana 30 mg/9 hour patch (methylphenidate)	30 units
Desoxyn 5 mg tablet (methamphetamine HCl)	150 units

Dexedrine 5 mg cap SA (dextroamphetamine sulfate)	90 units
Dexedrine 10 mg cap SA (dextroamphetamine sulfate)	180 units
Dexedrine 15 mg cap SA (dextroamphetamine sulfate)	120 units
Dextroamphetamine sulfate 5 mg tablet	90 units
Dextroamphetamine 10 mg tab	180 units
Focalin 2.5 mg tab (dexmethylphenidate)	60 units
Focalin 5 mg tab (dexmethylphenidate )	60 units
Focalin 10 mg tab (dexmethylphenidate)	60 units
Focalin XR 5 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 10 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 15 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 20 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 25 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 30 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 35 mg capsule (dexmethylphenidate HCl)	30 units
Focalin XR 40mg capsule (dexmethylphenidate HCl)	30 units
Intuniv ER 1 mg tablet (guanfacine HCl)	30 units
Intuniv ER 2 mg tablet (guanfacine hcl )	30 units
Intuniv ER 3 mg tablet (guanfacine HCl)	30 units
Intuniv ER 4 mg tablet (guanfacine HCl)	30 units
Kapvay 0.1mg	120 units
Kapvay 0.2mg	60 units
Metadate CD 10 mg capsule (methylphenidate HCl)	30 units
Metadate CD 20 mg capsule (methylphenidate HCl)	30 units
Metadate CD 30 mg capsule (methylphenidate HCl)	30 units

Metadate CD 40 mg capsule (methylphenidate HCl)	30 units
Metadate CD 50 mg capsule (methylphenidate HCl)	30 units
Metadate CD 60 mg capsule (methylphenidate HCl)	30 units
Metadate ER 10 mg tablet SA (methylphenidate HCl)	90 units
Metadate ER 20 mg/Ritalin sr (methylphenidate HCl)	90 units
methylin 2.5 mg chewable ta (methylphenidate HCl)	180 units
methylin 5 mg chewable tabl (methylphenidate HCl)	90 units
methylin 10 mg chewable tab (methylphenidate HCl)	180 units
methylin 10 mg/5 ml solution (methylphenidate HCl)	900ml
methylin 5 mg/5 ml solution (methylphenidate HCl)	1800ml
Ritalin 5 mg tablet (methylphenidate HCl)	90 units
Ritalin 10 mg tablet (methylphenidate HCl)	90 units
Ritalin 20 mg tablet (methylphenidate HCl)	90 units
Ritalin LA 10 mg capsule (methylphenidate HCl)	30 units
Ritalin LA 20 mg capsule (methylphenidate HCl)	90 units
Ritalin LA 30 mg capsule (methylphenidate HCl)	60 units
Ritalin LA 40 mg capsule (methylphenidate HCL)	30 units
Procentra 5 mg/5 ml solution (dextroamphetamine sulfate)	1800ml
Strattera 10 mg capsule (atomoxetine HCl)	60 units
Strattera 18 mg capsule (atomoxetine HCl)	60 units
Strattera 25 mg capsule (atomoxetine HCl)	60 units
Strattera 40 mg capsule (atomoxetine HCl)	60 units
Strattera 60 mg capsule (atomoxetine HCl)	30 units
Strattera 80 mg capsule (atomoxetine HCl)	30 units
Strattera 100 mg capsule (atomoxetine HCl)	30 units


Vyvanse 20 mg cap (lisdexamfetamine dimesylate)	30 units
Vyvanse 30 mg cap (lisdexamfetamine dimesylate)	30 units
Vyvanse 40 mg cap (lisdexamfetamine dimesylate)	30 units
Vyvanse 50 mg cap (lisdexamfetamine dimesylate)	30 units
Vyvanse 60 mg cap (lisdexamfetamine dimesylate)	30 units
Vyvanse 70 mg cap (lisdexamfetamine dimesylate)	30 units
Injectable fertility (Coverage is based on members benefit)	
Bravelle 75 unit vial	60 vials
Follistim AQ 75 unit vial	60 vials
Follistim AQ 150 unit vial	30 vials
Follistim AQ 300 unit cartridge	15 cartridges
Follistim AQ 600 unit Cartridge	8 cartridges
Follistim AQ 900 unit cartridge	5 cartridges
Gonal-F 450 units vial	10 vials
Gonal-F 1,050 unit vial	5 vials
Menopur 75 units vial	60 vials
Repronex 75 units vial	60 vials
Gonal-F RFF 300/0.5ml pen injector	15 pen injectors
Gonal-F RFF 450/0.75ml pen injector	10 pen injectors
Gonal-F RFF 900/1.5ml pen injector	5 pen injectors
Gonal-F RFF 75 unit vial	60 vials
<b>Proton pump inhibitors</b>	
Aciphex (rabeprazole) tab	30 units
Nexium (esomeprazole) caps, packet	30 units
Prevacid (lansoprazole) caps, solutab	30 units

Prilosec (omeprazole) caps, packet	30 units
Protonix (pantoprazole) tabs, packet	30 units
Dexilant (dexlansoprazole) caps	30 units
Zegerid (omeprazole/sod bicarb) caps, packet	30 units

Sprix [package insert] Roxro Pharma. Menlo Park CA. 2011.

Facts and Comparisons website [Proton pump inhibitors]. Available at [www.factsandcomparisons.com](http://www.factsandcomparisons.com). Accessed March 15, 2012.

**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.

5HT Receptor Agonists and Other Migraine Agent Quantity Limits - Refer to Migraine Agents Policy  
Quantity vs. Time Edits for Fertility Medications - Refer to Injectable Fertility Medications Policy  
Schedule II Tablet/Capsule/Lozenge/Patches Quantity Limits - Refer to Controlled Substance Quantity  
Limits Policy

Note: For retail plans with a 90-day supply or any mail service plans, the limits are tripled.

**Cross References:**

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