


## PHARMACY POLICY – 5.01.547

Medical Necessity Criteria and Dispensing Quantity Limits  
for Exchange Formulary Benefits

Effective Date:	Nov. 1, 2018	RELATED PHARMACY/MEDICAL POLICIES:
Last Revised:	Oct. 9, 2018	5.01.541 Medical Necessity Exception Criteria for Closed Formulary Benefits and Dispense as Written (DAW) Exception Reviews
Replaces:	N/A	5.01.605 Medical Necessity Criteria for Pharmacy Edits

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[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

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## Introduction

Step therapy is a way to provide safe and effective drugs. In step therapy, at least one drug on the health plan's list of covered drugs (the formulary) needs to be tried first. The first-use drugs are usually generic. A quantity limit is the amount of a specific drug that can be approved for a specific time period. This guideline describes the plan's step edits and quantity limits for specific drugs in the plan's formulary.

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

**Note:** This policy applies only to closed formulary pharmacy benefits designed to be sold on state and federal insurance exchanges. (See [Definition of Terms](#) below.) As used in this policy, "Formulary" refers to the applicable formulary list specified in a member's contract. The policy

does not apply to open benefit designs in which non-formulary drugs are covered, though in some cases at a higher tier.

New regulatory requirements generated by implementation of the Affordable Care Act and the resulting creation of federal and state insurance exchanges have led to the creation of novel pharmacy benefit designs that differ substantially in structure, breadth of formularies and utilization management requirements. The following additional criteria will apply to these benefits:

Medical Necessity Review	
Drug	Medical Necessity
<b>Actimmune® (interferon gamma-1b)</b>	<p><b>Actimmune® (interferon gamma-1b) may be considered medically necessary for:</b></p> <ul style="list-style-type: none"> <li>• Chronic granulomatous disease</li> <li>• Severe malignant osteopetrosis</li> </ul>
<b>Leukine® (sargramostim)</b>	<p><b>Leukine® (sargramostim) may be considered medically necessary for:</b></p> <ul style="list-style-type: none"> <li>• Acute myelogenous leukemia (following induction chemotherapy)</li> <li>• Mobilization and following transplantation of autologous peripheral blood progenitor cells</li> <li>• Myeloid reconstitution after (allogenic or autologous) bone marrow transplantation</li> <li>• Bone marrow transplantation (allogenic or autologous) failure or engraftment delay</li> </ul>
<b>Jakafi® (ruxolitinib)</b>	<p><b>Jakafi® (ruxolitinib) may be considered medically necessary for:</b></p> <ul style="list-style-type: none"> <li>• Myelofibrosis</li> <li>• Polycythemia vera, after trial and failure of hydroxyurea</li> </ul>
<b>Ilaris® (canakinumab)</b>	<p><b>Ilaris® (canakinumab) may be considered medically necessary for:</b></p> <ul style="list-style-type: none"> <li>• Periodic fever syndromes <ul style="list-style-type: none"> <li>○ Cryopyrin-associated periodic syndromes (CAPS)</li> <li>○ Familial Mediterranean Fever (FMF)</li> <li>○ Hyperimmunoglobulin D syndrome (HIDS)/mevalonate kinase deficiency (MKD)</li> <li>○ Tumor necrosis factor receptor associated periodic syndrome (TRAPS)</li> </ul> </li> </ul>



## Medical Necessity Review

Drug	Medical Necessity
	<ul style="list-style-type: none"> <li>Systemic juvenile idiopathic arthritis</li> </ul>

## Step Therapy Protocol

**A step therapy edit is a requirement that one or more specified first step agents be tried and failed before coverage will be provided for another second step agent.**

**Manual review for medical necessity is required, based on the following criteria:**

- Use of a second step agent may be considered medically necessary when the prescribing provider has documented that the required number of first step agents were tried and these agents were ineffective, not tolerated or contraindicated.

**OR**

- Use of a second step agent may be considered medically necessary when the prescribing provider has documented a patient-specific reason why this agent should be used as first-line therapy. These requests will be evaluated on a case-by-case basis.

## Drugs Subject to the Step Therapy Protocol

Drug Class	Second Step Drugs	First Step Agents
Fluoroquinolones	Factive	ciprofloxacin, levofloxacin, moxifloxacin
Antiemetics	Anzemet	ondansetron, granisetron
	Cesamet	dexamethasone, granisetron, metoclopramide, ondansetron
Inhaled Antibiotics	Cayston	tobramycin (inhaled)
Nitroglycerin	Minitran, Nitro-Dur	nitroglycerin patch
Opioids, Long-acting	Nucynta ER	morphine ER, OxyContin, fentanyl transdermal, tramadol hcl ER
Opioids, Short-acting	Nucynta, Oxecta	morphine sulfate, oxycodone, hydromorphone, tramadol hcl
Overactive Bladder	Myrbetriq, Toviaz, Vesicare	oxybutynin chloride, tolterodine, trospium
Topicals, Corticosteroid	U-Cort	hydrocortisone + urea
Respiratory	Ventolin HFA	Proair
Pain	Butrans	1 non-opioid medication (i.e. gaba-analogues, tricyclic antidepressants, SNRI's, NSAID's, etc.) AND 1 immediate-release opioid (i.e. oxycodone, morphine, hydromorphone, etc.)



## Drugs Subject to the Step Therapy Protocol

Drug Class	Second Step Drugs	First Step Agents
Acne	Epiduo forte, Tazorac, tazarotene	Generic benzoyl peroxide/clindamycin gel, AND generic topical tretinoin cream or gel, AND a generic tetracycline (doxycycline or minocycline)
Anti-platelet	Brilinta	Clopidogrel
Anti-hypertensive	Bystolic	Trial and failure of two preferred medications: metoprolol, atenolol, or bisoprolol
Anti-lipemic	Welchol	Trial and failure of two preferred medications: colestipol, cholestyramine, or Prevalite
Ophthalmic corticosteroids	Lotemax	Trial and failure of two preferred medications: prednisolone, dexamethasone, or FML eye drops
Angina	Ranexa	Trial and failure of at least 2 generic beta-blockers
Antidepressant	Emsam	Trial and failure of two preferred medications: generic SSRI and/or a generic SNRI
Bowel preps	Suprep	Generic PEG solution

## Dispensing Quantity Limits

The following dispensing quantity limits are based on the maximum dose recommendations in the product's FDA-approved labeling. This information is available for each product at the manufacturer's web site or [www.fda.gov](http://www.fda.gov). Drugs with Dispensing Quantity Limits are listed in the following table:

Drug	Dosage / Strength	Quantity Limit
Advair Diskus	100/50 with device (14 blister diskus)	Limit: 14 blisters per fill
Advair Diskus	100/50 with device (28 blister diskus)	Limit: 28 blisters per fill
Advair Diskus	100/50 with device (60 blister diskus)	Limit: 1 device per fill
Advair Diskus	250/50 with device (14 blister diskus)	Limit: 14 blisters per fill
Advair Diskus	250/50 with device (28 blister diskus)	Limit: 28 blisters per fill
Advair Diskus	250/50 with device (60 blister diskus)	Limit: 1 device per fill
Advair Diskus	500/50 with device (14 blister diskus)	Limit: 14 blisters per fill
Advair Diskus	500/50 with device (28 blister diskus)	Limit: 28 blisters per fill
Advair Diskus	500/50 with device (60 blister diskus)	Limit: 1 device per fill
Advair HFA (120)	45/21 mcg	Limit: 1 device per fill



Drug	Dosage / Strength	Quantity Limit
Advair HFA (120)	115/21 mcg	Limit: 1 device per fill
Advair HFA (120)	230/21 mcg	Limit: 1 device per fill
Advair HFA (60)	45/21 mcg	Limit: 1 device per fill
Advair HFA (60)	115/21 mcg	Limit: 1 device per fill
Advair HFA (60)	230/21 mcg	Limit: 1 device per fill
Aerospan	80mcg/inh (8.9g)	Limit: 2 inhalers per fill
Akynzeo	300-0.5mg	Limit: 1 capsule per fill
Alora	0.025 mg/day patch	Limit: 8 patches per 30 days
Alora	0.05 mg/day patch	Limit: 8 patches per 30 days
Alora	0.075 mg/day patch	Limit: 8 patches per 30 days
Alora	0.1 mg/day patch	Limit: 8 patches per 30 days
Alvesco	160 mcg (120 actuations) 9.6 g canister	Limit: 1 inhaler per fill
Alvesco	160 mcg(60 actuations) 6.1 g canister	Limit: 2 inhalers per fill
Alvesco	80 mcg (60 actuations) 6.1g canister	Limit: 1 inhaler per fill
Anzemet	50 mg tablet	Limit:3 tablets per fill
Anzemet	100 mg tablet	Limit: 3 tablets per fill
Arnuity Ellipta	100mcg (14 blisters)	Limit: 1 inhaler per fill
Arnuity Ellipta	100mcg (30 blisters)	Limit: 1 inhaler per fill
Arnuity Ellipta	200mcg (14 blisters)	Limit: 1 inhaler per fill
Arnuity Ellipta	200mcg (30 blisters)	Limit: 1 inhaler per fill
Asmanex HFA	100mcg/inh	Limit: 1 inhaler per fill
Asmanex HFA	200mcg/inh	Limit: 1 inhaler per fill
Asmanex Twisthaler	110 mcg/inh (7 inhalations)	Limit: 1 inhaler per fill
Asmanex Twisthaler	110 mcg/inh (14 inhalations)	Limit: 1 inhaler per fill
Asmanex Twisthaler	110 mcg/inh (30 inhalations)	Limit: 1 inhaler per fill
Asmanex Twisthaler	220 mcg/inh (14 inhalations)	Limit: 1 inhaler per fill
Asmanex Twisthaler	220 mcg/inh (30 inhalations)	Limit: 1 inhaler per fill
Asmanex Twisthaler	220 mcg/inh (60 inhalations)	Limit: 1 inhaler per fill
Asmanex Twisthaler	220 mcg/inh (120 inhalations)	Limit: 1 inhaler per fill
Atrovent HFA	12.9 gm Aerosol	Limit: 2 inhalers per fill



Drug	Dosage / Strength	Quantity Limit
Avonex	30 mcg prefilled syringe	Limit: 4 syringes per 30 days
Avonex	30 mcg vial	Limit: 4 vials per 30 days
Avonex Admin Pack	30 mcg	Limit: 4 kits per 30 days
Avonex Pen	30 mcg/0.5 ml pen	Limit: 1 box (4 pens) per 30 days
Betaseron	0.3 mg vial	Limit: 14 prefilled diluent syringes per 30 days
Cesamet	1 mg capsule	Limit: 30 capsules per fill
Climara (estradiol)	0.025 mg/day patch	Limit: 4 patches per 30 days
Climara (estradiol)	0.0375 mg/day patch	Limit: 4 patches per 30 days
Climara (estradiol)	0.05 mg/day patch	Limit: 4 patches per 30 days
Climara (estradiol)	0.06 mg/day patch	Limit: 4 patches per 30 days
Climara (estradiol)	0.075 mg/day patch	Limit: 4 patches per 30 days
Climara (estradiol)	0.1 mg/day patch	Limit: 4 patches per 30 days
Climara Pro	0.045 mg/ 0.015 mg/day patch	Limit: 4 patches per 30 days
Combivent Respimat	20mcg-100mcg	Limit: 2 inhalers per fill
Copaxone (glatiramer)	20 mg prefilled syringe	Limit: 1 kit (30 prefilled syringes) per 30 days
Copaxone (glatiramer)	40 mg prefilled syringe	Limit: 12 per 30 days
Divigel	0.1% (0.25 g/packet)	Limit: 30 packets per fill
Divigel	0.1% (0.5 g/packet)	Limit: 30 packets per fill
Divigel	0.1% (1g/packet)	Limit: 30 packets per fill
Duetact	30/2mg tablet	Limit: 30 tablets per fill
Duetact	30/4mg tablet	Limit: 30 tablets per fill
Dulera	100mcg/5mcg	Limit: 1 inhaler per fill
Dulera	200mcg/5mcg	Limit: 1 inhaler per fill
Elestrin gel	0.06% gel meter dose pump	Limit: 52 grams (2 pumps) per fill
Emend	40 mg capsule	Limit: 1 capsule per fill
Emend	80 mg capsule	Limit: 2 capsules per fill
Emend	125 mg capsule	Limit: 1 capsule per fill
Emend	150mg injection	Limit: 1 vial per fill
Emend	Bifold pack	Limit: 1 pack per fill



Drug	Dosage / Strength	Quantity Limit
Emend	Trifold Pack, contains one 125 mg and two 80 mg capsules	Limit: 1 pack (package size 3) per fill
Estraderm	0.05 mg/day patch	Limit: 8 patches per 30 days
Estraderm	0.1 mg/day patch	Limit: 8 patches per 30 days
Estrasorb	4.35 mg per 1.74 g pouch	Limit: 56 packets (97.44 g) per fill
Estrogel	0.06% 50 gm pump	Limit: 1 pump per fill
Evamist	1.53 mg spray	Limit: 2 pumps per fill
Extavia	0.3 mg kit	Limit: 15 blister units/vials per 30 days
Extavia	0.3 mg vial	Limit: 15 blister units/vials per 30 days
Flovent Diskus	Powder 100mcg (1 device = 60 doses)	Limit: 1 inhaler per fill
Flovent Diskus	Powder 250mcg (1 device = 60 doses)	Limit: 4 inhalers per fill
Flovent Diskus	Powder 50mcg (1 device = 60 doses)	Limit: 1 inhaler per fill
Flovent HFA	Aerosol 10.6 gm (120 doses; 44 mcg/dose)	Limit: 1 inhaler per fill
Flovent HFA	Aerosol 12 gm (120 doses; 110 mcg/dose)	Limit: 1 inhaler per fill
Flovent HFA	Aerosol 12 gm (120 doses; 220 mcg/dose)	Limit: 2 inhalers per fill
Granisetron	1 mg tablet	Limit: 6 tablets per fill
Incruse Ellipta	62.5mcg (7 blister)	Limit: 1 inhaler per fill
Incruse Ellipta	62.5mcg (30 blister)	Limit: 1 inhaler per fill
Ipratropium/albuterol	3ml vial	Limit: 180 vials per fill
Menostar	14 mcg/day patch	Limit: 4 patches per 30 days
Minivelle	0.0375 mg patch	Limit: 8 patches per 30 days
Minivelle	0.05 mg patch	Limit: 8 patches per 30 days
Minivelle	0.075 mg patch	Limit: 8 patches per 30 days
Minivelle	0.1 mg patch	Limit: 8 patches per 30 days
Plegridy	125mcg/0.5ml pen	Limit: 2 pens per 30 days
Plegridy	63/94mcg starter pack	Limit: 1 starter pack per 365 days
Pulmicort Flexhaler	90mcg/actuation	Limit: 1 inhalers per fill
Pulmicort Flexhaler	180mcg/actuation	Limit: 2 inhaler per fill
Pulmicort Respules (budesonide)	0.25mg/2 mL	Limit: 60 respules per fill



Drug	Dosage / Strength	Quantity Limit
Pulmicort Respules budesonide)	0.5mg/2 mL	Limit: 60 respules per fill
Pulmicort Respules budesonide)	1mg/2 mL	Limit: 30 respules per fill
Qvar HFA	40mcg	Limit: 2 inhalers per fill
Qvar HFA	80mcg	Limit: 3 inhalers per fill
Rebif	22mcg syringe	Limit: 12 syringes per 30 days
Rebif	44mcg syringe	Limit: 12 syringes per 30 days
Rebif	Titration pack	Limit: 1 package per 30 days
Relenza	5 mg Diskhaler	Limit: 40 blisters (2 cartons) per 365 days
Sancuso	3.1 mg/24 hour patch	Limit: 1 patch per fill
Spiriva	18 mcg capsule for use with inhalation device, 30 capsules	Limit: 1 package per fill
Spiriva	18 mcg capsule for use with inhalation device, 5 capsules (1 blister card)	Limit: 1 package per fill
Spiriva	18 mcg capsule for use with inhalation device, 90 capsules (6 blister cards)	Limit: 1 package (90 doses) per fill
Spiriva Respimat	4gm inhaler (28 spray)	Limit: 1 inhaler per fill
Spiriva Respimat	4gm inhaler (60 spray)	Limit: 1 inhaler per fill
Symbicort	80/4.5 mcg inhaler	Limit: 1 package per fill
Symbicort	160/4.5 mcg inhaler	Limit: 1 package per fill
Tamiflu	6 mg/ml suspension	Limit: 6 bottles per 365 days
Tamiflu	12 mg/ml suspension	Limit: 6 bottles per 365 days
Tamiflu	30 mg capsule	Limit: 40 capsules per 365 days
Tamiflu	45 mg capsule	Limit: 20 capsules per 365 days
Tamiflu	75 mg capsule	Limit: 20 capsules per 365 days
Tudorza Pressair	400 mcg inhaler	Limit: 1 inhaler per fill
Vivelle (estradiol)	0.025 mg patch	Limit: 8 patches per 30 days
Vivelle (estradiol)	0.0375 mg patch	Limit: 8 patches per 30 days
Vivelle (estradiol)	0.05 mg patch	Limit: 8 patches per 30 days
Vivelle (estradiol)	0.075 mg patch	Limit: 8 patches per 30 days
Vivelle (estradiol)	0.1 mg patch	Limit: 8 patches per 30 days
Vivelle-Dot (estradiol)	0.025 mg patch	Limit: 8 patches per 30 days





Drug	Dosage / Strength	Quantity Limit
Vivelle-Dot (estradiol)	0.0375 mg patch	Limit: 8 patches per 30 days
Vivelle-Dot (estradiol)	0.05 mg patch	Limit: 8 patches per 30 days
Vivelle-Dot (estradiol)	0.075 mg patch	Limit: 8 patches per 30 days
Vivelle-Dot (estradiol)	0.1 mg patch	Limit: 8 patches per 30 days
Zofran (ondansetron)	4 mg tablet	Limit: 9 tablets per fill
Zofran (ondansetron)	8 mg tablet	Limit: 9 tablets per fill
Zofran (ondansetron)	24 mg tablet	Limit: 1 tablet per fill
Zofran (ondansetron)	4mg/5ml solution	Limit: 2 bottles per fill
Zofran ODT (ondansetron ODT)	4 mg tablet	Limit: 9 orally disintegrating tab per fill
Zofran ODT (ondansetron ODT)	8 mg tablet	Limit: 9 orally disintegrating tab per fill
Zubsolv	1.4 mg/0.36 mg tablet	Limit: 90 tablets per fill
Zubsolv	5.7 mg/1.4 mg tablet	Limit: 90 tablets per fill
Zubsolv	8.6mg/2.1mg tablet	Limit: 60 tablets per fill
Zuplenz	4 mg soluble film	Limit: 9 films per fill
Zuplenz	8 mg soluble film	Limit: 9 films per fill
Zinbryta	150mg/mL	Limit: 1 syringe per 30 days



## Antiretroviral Quantity Limits per 30 Days

The following quantity limits per 30 days are based on the maximum dose recommendations in the product's FDA-approved labeling. This information is available for each product at the manufacturer's web site or [www.fda.gov](http://www.fda.gov).

Drug	Dosage/Strength	Quantity Limit
Abacavir	20mg/ml	Limit: 60 mL per 30 days
Abacavir	300mg	Limit: 60 Tablets per 30 days
Abacavir-Lamivudine	600-300mg	Limit: 30 Tablets per 30 days
Aptivus	100mg/ml	Limit: 5700 mL per 30 days
Aptivus	250mg	Limit: 120 Capsules per 30 days
Atazanavir	All	Limit: 30 Capsules per 30 days
Atripla	All	Limit: 30 Tablets per 30 days
Biktarvy	All	Limit: 30 Tablets per 30 days
Cimduo	All	Limit: 30 Tablets per 30 days
Combivir	All	Limit: 60 Tablets per 30 days
Complera	All	Limit: 30 Tablets per 30 days
Crixivan	All	Limit: 180 Capsules per 30 days
Delstrigo	100-300mg	Limit: 30 Tablets per 30 days
Descovy	All	Limit: 30 Tablets per 30 days
Didanosine dr	All	Limit: 30 Capsules per 30 days
Edurant	All	Limit: 30 Tablets per 30 days
Efavirenz	All	Limit: 30 Tablets/Capsules per 30 days
Emtriva	10mg/mL	Limit: 20,400 mL per 30 days
Emtriva	200mg	Limit: 30 Capsules per 30 days
Eпивir	10mg/mL	Limit: 30 mL per 30 days
Eпивir	150mg and 300mg	Limit: 30 Tablets per 30 days
Evotaz	All	Limit: 30 Tablets per 30 days
Fosamprenavir	All	Limit: 60 Tablets per 30 days
Fuzeon	All	Limit: 30 Vials per 30 days
Genvoya	All	Limit: 30 Tablets per 30 days



Drug	Dosage/Strength	Quantity Limit
Intelence	All	Limit: 60 Tablets per 30 days
Invirase	All	Limit: 120 Tablets/Capsules per 30 days
Isentress	All	Limit: 60 per 30 days
Isentress HD	All	Limit: 60 Tablets per 30 days
Juluca	All	Limit: 30 Tablets per 30 days
Kaletra	100-25mg	Limit: 60 Tablets per 30 days
Kaletra	200-50mg	Limit: 120 Tablets per 30 days
Kaletra	80-20mg/mL	Limit: 320 mL per 30 days
Lexiva	50mg/mL	Limit: 60 mL per 30 days
Nevirapine	200mg	Limit: 60 Tablets per 30 days
Nevirapine	All	Limit: 60 mL per 30 days
Nevirapine ER	All	Limit: 30 Tablets per 30 days
Norvir	100mg	Limit: 30 packets per 30 days
Norvir	100mg	Limit: 360 Tablets/Capsules per 30 days
Norvir	80mg/mL	Limit: 480 mL per 30 days
Odefsey	All	Limit: 30 Tablets per 30 days
Pifeltro	100mg	Limit: 30 Tablets per 30 days
Prezcobix	All	Limit: 30 Tablets per 30 days
Prezista	100mg/mL	Limit: 30 mL per 30 days
Prezista	75mg, 150 mg, 400mg, 600mg	Limit: 60 Tablets per 30 days
Prezista	800mg	Limit: 30 Tablets per 30 days
Rescriptor	All	Limit: 90 Tablets per 30 days
Retrovir	100mg	Limit: 60 Capsules per 30 days
Retrovir	10mg/ml	Limit: 960 mL per 30 days
Reyataz	50mg	Limit: 30 packets per 30 days
Selzentry	20mg/ml	Limit: 1840 mL per 30 days
Selzentry	All	Limit: 60 Tablets per 30 days
Stavudine	1mg/mL	Limit: 2,400 mL per 30 days
Stavudine	All	Limit: 120 Capsules per 30 days
Stribild	All	Limit: 30 Tablets per 30 days



Drug	Dosage/Strength	Quantity Limit
Symfi	All	Limit: 30 Tablets per 30 days
Symfi Lo	All	Limit: 30 Tablets per 30 days
Tenofovir Disoproxil	All	Limit: 30 Tablets per 30 days
Tivicay	All	Limit: 60 Tablets per 30 days
Triumeq	All	Limit: 30 Tablets per 30 days
Trizivir	300-150-300mg	Limit: 60 Tablets per 30 days
Truvada	All	Limit: 30 Tablets per 30 days
Tybost	All	Limit: 30 Tablets per 30 days
Videx	All	Limit: 300 mL per 30 days
Viracept	250mg	Limit: 90 Tablets per 30 days
Viracept	625mg	Limit: 60 Tablets per 30 days
Viread	All	Limit: 30 per 30 days
Vitekta	All	Limit: 30 Tablets per 30 days

## Coding

N/A

## Related Information

### Definition of Terms

**Closed formulary benefit:** A closed formulary benefit is one that routinely covers only formulary (preferred) drugs. A non-formulary drug may be covered when its use has been determined to be medically necessary after a review of the individual clinical case circumstances.

**Formulary:** A formulary is a list of drugs approved by the Pharmacy and Therapeutics Committee (P&T) for routine use. A well-designed formulary should provide adequate drug



selection to meet the treatment needs of most patients; however, there will always be exceptional cases where a non-formulary drug may be the best therapeutic choice.

**Formulary drug:** A formulary drug (also known as a preferred drug) is a drug that is on the formulary list. Drugs that are not on the list are referred to as non-formulary drugs.

**Label:** Product label refers to the FDA approved prescribing information that is available for every legend drug approved for use in the U.S. The label includes indications, contraindications, recommended dosing, warnings, precautions, side effects, drug interactions and information on safety in pregnancy and other special populations. The drug's pharmacology, pharmacokinetics, and available dosage forms are also provided. The current format also includes a summary of the pivotal clinical trials that were submitted to FDA in support of the New Drug Application.

This prescribing information is included as a package insert with the product and is available on the manufacturer's Web site.

**Quantity limits:** A quantity limit is the maximum amount of a medication that may be dispensed during a given calendar period or at one prescription fill without an exception request. Dispensing of a larger quantity may be approved, based on individual case review. A specified larger quantity may be approved when patient-specific circumstances require it, or when published clinical evidence supports a higher dose protocol.

**Note:** Dispensing quantity limits are not intended to apply in circumstances where logistics may dictate otherwise. These circumstances include but are not limited to member vacation or business travel, disruption of normal prescription supply chains due to adverse weather events or other disasters and members living in remote areas where travel to the nearest pharmacy may sometimes be problematic.

**Step therapy:** A step therapy edit is a requirement that one or more specified first step agents be tried and failed before coverage will be provided for another second step agent. Step therapy requirements are based upon evidence from published, peer-reviewed clinical studies demonstrating that first-line use of the first step agents is clinically reasonable in most circumstances.

## Benefit Application

The drugs addressed in this policy are managed through the Pharmacy benefit.



## Rationale

Step therapy edits are designed to channel utilization toward drugs that are at least as safe and effective and lower cost than other similar drugs that are also available. In many cases, the first step drugs in a particular edit algorithm are generics and the second step alternatives are brands that are more expensive and offer no proven incremental clinical benefit compared to the first step drugs. Step therapy, prior authorization and other similar utilization management tools are designed to steer members toward more cost-effective therapeutic choices and are thus an important component of affordable benefit designs.

Recent trends in prescription drug prices in the United States have led to an increased pressure on health care providers to keep down the cost of prescription medication while maintaining high levels of availability to the patient. Mandatory controls will become more important in plan designs that meet the Essential Health Benefit (EHB) requirements of the Affordable Care Act. In making care more accessible to members, the EHB requirements limit some of the financial incentives that have been developed to incent members to select lower cost alternatives. Furthermore, many manufacturers provide copay coverage, eliminating any additional cost impact to the member. Well designed and clinically based step therapy programs thus encourage proper drug selection without negative effects on members.

Motheral and colleagues published a retrospective database analysis of three step therapy programs implemented in a 20,000 member plan in 2002. The three edits targeted proton pump inhibitors, selective serotonin reuptake inhibitors and nonsteroidal anti-inflammatory drugs, respectively. The investigators studied two years' worth of pharmacy claims of the intervention group against a comparator group of members from similar plans that did not have the three step therapy programs. Per member per month costs (PMPM) decreased by \$0.83 in the intervention group, compared to a \$0.10 rise on in the comparator group. A mailed self-administered member survey found that 30% received a generic, 23% were granted an exception and received the originally requested drug, 16% paid the full prescription price and 17% received no drug. Patients were 8 times more likely to receive a covered medication when the pharmacist called the prescriber. Failure to receive a covered medication reduced member satisfaction. The authors concluded that step therapy programs do reduce plan cost, but improving members' and providers' understanding of the programs would improve their outcomes and member satisfaction.<sup>1</sup>

A major objection to step therapy and other prior authorization programs has always been the administrative effort by provider office staff required to process exception requests. Historically, studies that attempted to measure this have reported conflicting results. A recent study by



Morley, et al. estimated an average annual cost of \$2,161 to \$3,430 per clinic physician FTE. Over 50% of the staff time spent on prior authorization processing was by clerical staff. Less than 10% was by physicians, the remainder being provided by nurses and physician assistants.<sup>2</sup> The authors believe that further analysis is warranted, and with the expected improvement in ubiquity and interoperability of health information systems, it is likely that the administrative effort will be further reduced. A small convenience sample study at the Cambridge Health Alliance psychiatric emergency department found that prior authorization requirements for medications did add much to the time spent in ER prior to discharge.<sup>3</sup>

Prior authorization, step therapy and quantity limits are typical features of managed Medicare and Medicaid programs. Soumerai and colleagues, Hoadley and others have studied the effect of these interventions and generally report that they save plan cost and move utilization toward lower cost generic and preferred brand drugs without major impact on adherence.<sup>4-6</sup>

Quantity limits in this policy are based on maximum FDA approved dose as stated in the product label. These limits represent the upper bound of the dose range that has been shown to balance safety and efficacy as demonstrated by clinical trial data contained in the New Drug Application (NDA) or supplemental application (sNDA) for higher labeled dosing.<sup>7</sup> Quantities in excess of the limits in this policy may be approved based on adequate evidence from published peer reviewed clinical studies.

## 2018 Update

Review of current FDA labeling. Added Leukine indication for myeloid reconstitution after autologous bone marrow transplantation. No other changes required.

## References

1. Motheral BR, Henderson R, Cox ER. Plan sponsor savings and member experience with point-of-service prescription step therapy. *Am J Manag Care* 2004;10:457-464.
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11. Ilaris Prescribing Information. Novartis. East Hanover, NJ. Revised: 12/16.

## History

Date	Comments
09/09/13	New policy, add to Prescription Drug section.
12/09/13	Replace policy. Policy section reflects updates to the Step Therapy and Dosing Limits tables.
03/10/14	Annual Review. Step Therapy Protocol and Dosing Limit Tables updated within the Policy section.
04/14/14	Interim Review. Step Therapy Protocol and Dosing Limit Tables updated within the Policy section. Sedative hypnotic drugs quantity level limit for 30-day period added to the Policy Guidelines section.
08/11/14	Interim Update. Formulary table updated; Myrbetriq added to the list of approved second-step agents for overactive bladder; Ibuprofen and meloxicam replaced with diclofenac, generic NSAIDs under miscellaneous topicals; Hetlioz removed from the dosing table (addressed in a separate policy). Policy Guidelines updated within the Sedative Hypnotic Drugs Quantity Level Limit for 30-Day Period section.
12/08/14	Interim Review. Covered to Benefit Coverage Guideline template. Coverage criteria updated within the step-therapy table in the Coverage Guideline section.
01/13/15	Annual Review. Dispensing quantity limits table updated within the Policy section; Plegridy and Trulicity added.
02/10/15	Interim Review. Quantity limits updated on Relenza and Tamiflu to indicate the quantities are per 365 days and not per 30 days as previously indicated.
03/10/15	Interim Review. Updated quantity limits added to drugs as appropriate; drugs for which a PA is no longer required removed from the policy.





Date	Comments
04/14/15	Interim Review. Updated quantity limits added to drugs as appropriate; drugs for which a PA is no longer required removed from the policy; new drugs added which are now on the PA list.
06/09/15	Interim Review. Step therapy table updated; anticoagulants and corticosteroid ApexiCon E removed. Dosing table updated with the removal of Alendronate, Ambien, Ambien CR, Atelvia, Dalmane, Doral, Edluar, Halcion, Intermezzo, Lunesta, Prosom, Restoril, Rozerem, Silenor, Sonata, and Zolpimist. Information stricken regarding sedative hypnotic drug quantity level limits.
08/11/15	Interim Update. Chantix removed edit as of 7/21/15, and Beta agonist inhalers: removed quantity limit as of 7/21/15.
10/13/15	Interim Update. Removed Lofibra and Tricor from Fibrate step edit as they are no longer formulary medications; removed Azelex, Finacea, Tazorac, Tretin-X from the Acne Topical section as housekeeping as these edits have been removed but policy was not updated; removed Ala-Scalp from Corticosteroid Topical section as it is no longer a formulary medication; removed Cortane-B and Vectical from Misc Topical section as they are no longer formulary medications; removed Triptans from this policy as the step edit has been retired from this policy; removed ActoPlus Met, Actos, Avandamet, Avandia, Avandryl, Bydureon, Byetta, Farxiga, Invokana, Invokamet, Janumet, Janumet XR, Januvia, Jardiance, Jentadueto, Kazano, Kombiglyze XR, Nesina, Onglyza, Oseni, PrandiMet, Symlin, Tradjenta, Trulicity, Victoza and Xigduo as the quantity limit rule is being removed; removed Brovana as housekeeping as the quantity limit was previously moved but medical policy was not updated; added generic name of estradiol to Vivelle as there is now a generic available that is also targeted under quantity limit rule.
02/09/16	Annual Review. Policy updated; the following drugs were removed since there is no longer an edit: Ultravate PAC, Analpram-E, Lac-Hydrin, Momexin, and Voltaren Gel.
07/01/16	Interim Update, approved June 14, 2016. Crestor and Livalo removed from step edit as of 6/15/16; Cholesterol medications removed from quantity limit as of 6/15/16; Enablex and Synalar Solution removed from step edit as of 7/1/16 due to change to non-formulary status.
01/01/17	Interim Review, approved December 13, 2016. Removal of the quantity limits for the trans-mucosal fentanyl products (TURFs) due to implementation of the diagnosis-based edit for those products. Addition of the quantity limit for Zinbryta used for Multiple Sclerosis.
03/01/17	Annual Review, approved February 14, 2017. Copaxone 40mg quantity limit was added to the table, while Forteo quantity limit was removed. Also, removed Fenoglide and Lipofen from step-therapy table.
07/01/17	Benefit Coverage Guideline moved into new format. No changes to policy statement.
12/01/17	Interim Review, approved November 9, 2017. Added generic glatiramer.
01/01/18	Interim Review, approved December 12, 2017. Added new medications to be targeted



Date	Comments
	on 1/1/18 (Actimmune, Leukine, Jakafi, Ilaris, Ventolin HFA, colchicine, Butrans, Epiduo Forte, Tazorac, tazarotene, Brilinta, Welchol, Lotemax, Ranexa, Emsam, Suprep).
02/01/18	Annual Review, approved January 30, 2018. Review of current FDA labeling; no changes to policy statements.
05/01/18	Interim Review, approved April 18, 2018. Review of current FDA labeling. Added Leukine indication for myeloid reconstitution after autologous bone marrow transplantation.
07/01/18	Interim Review, approved June 22, 2018. Updated indication and first-step agents for Emsam.
09/01/18	Interim Review, approved August 23, 2018. Removed Colchicine from policy.
11/01/18	Interim Review, approved October 9, 2018. Policy updated with HIV drug quantity limits and removed opioid quantity limits.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2018 Premera All Rights Reserved.

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Premera:

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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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Civil Rights Coordinator - Complaints and Appeals  
PO Box 91102, Seattle, WA 98111  
Toll free 855-332-4535, Fax 425-918-5592, TTY 800-842-5357  
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services  
200 Independence Avenue SW, Room 509F, HHH Building  
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)  
Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>.

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**This Notice has Important Information.** This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

**አማርኛ (Amharic):**

ይህ ማስታወቂያ አስፈላጊ መረጃ ይዟል። ይህ ማስታወቂያ ስለ ማመልከቻዎ ወይም የ Premera Blue Cross ሽፋን አስፈላጊ መረጃ ሊኖረው ይችላል። በዚህ ማስታወቂያ ውስጥ ቁልፍ ቀናት ሊኖሩ ይችላሉ። የጤና ሽፋንዎን ለመጠበቅና በአስፋፈል እርዳታ ለማግኘት በተውሰኑ የጊዜ ገደቦች እርምጃ መውሰድ ይገባዎት ይሆናል። ይህን መረጃ እንዲያገኙ እና የለምንም ክፍያ በቋንቋዎ እርዳታ እንዲያገኙ መሰታ አለዎት። በስልክ ቁጥር 800-722-1471 (TTY: 800-842-5357) ይደውሉ።

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**ភាសាខ្មែរ (Khmer):**

សេចក្តីជូនដំណឹងនេះមានព័ត៌មានយ៉ាងសំខាន់។ សេចក្តីជូនដំណឹងនេះប្រហែលជាមានព័ត៌មានយ៉ាងសំខាន់អំពីទម្រង់បែបបទ ឬការរៀបចំរបស់អ្នកកាមរយ: Premera Blue Cross ។ ប្រហែលជាមាន កាលបរិច្ឆេទសំខាន់នៅក្នុងសេចក្តីជូនដំណឹងនេះ។ អ្នកប្រហែលជាត្រូវការបញ្ជាក់សមត្ថភាព ដល់កិច្ចការផ្ទៃក្នុងដូចជា ឆ្លើយតបនឹងសំណួរ ឬការបញ្ជាក់ការបំពេញសេចក្តីជូនដំណឹងនេះ។ អ្នកមានសិទ្ធិទទួលបានព័ត៌មាននេះ និងដំណោះស្រាយសេចក្តីជូនដំណឹងនេះ ដោយមិនអស់លុយឡើយ។ សូមទូរស័ព្ទ 800-722-1471 (TTY: 800-842-5357)។

**ਪੰਜਾਬੀ (Punjabi):**

ਇਸ ਨੋਟਿਸ ਵਿਚ ਖਾਸ ਜਾਣਕਾਰੀ ਹੈ. ਇਸ ਨੋਟਿਸ ਵਿਚ Premera Blue Cross ਵਲੋਂ ਤੁਹਾਡੀ ਕਵਰੇਜ ਅਤੇ ਅਰਜੀ ਬਾਰੇ ਮਹੱਤਵਪੂਰਨ ਜਾਣਕਾਰੀ ਹੋ ਸਕਦੀ ਹੈ . ਇਸ ਨੋਟਿਸ ਨਵ ਖਾਸ ਤਾਰੀਖਾਂ ਹੋ ਸਕਦੀਆਂ ਹਨ. ਜੇਕਰ ਤੁਸੀਂ ਜਸਰਤ ਕਵਰੇਜ ਰਿੱਖਣੀ ਹੋਵੇ ਜਾਂ ਓਸ ਦੀ ਲਾਗਤ ਜਵਿੱਚ ਮਦਦ ਦੇ ਇਛੁੱਕ ਹੋ ਤਾਂ ਤੁਹਾਨੂੰ ਅੰਤਮ ਤਾਰੀਖ ਤੋਂ ਪਹਿਲਾਂ ਢੁੱਝ ਖਾਸ ਕਰਮ ਚੁੱਕਣ ਦੀ ਲੋੜ ਹੋ ਸਕਦੀ ਹੈ ,ਤੁਹਾਨੂੰ ਮੁਫਤ ਵਿੱਚ ਤੋਂ ਅਪਣੀ ਭਾਸ਼ਾ ਵਿੱਚ ਜਾਣਕਾਰੀ ਅਤੇ ਮਦਦ ਪ੍ਰਾਪਤ ਕਰਨ ਦਾ ਅਧਿਕਾਰ ਹੈ ,ਕਾਲ 800-722-1471 (TTY: 800-842-5357).

**فارسی (Farsi):**

این اعلامیه حاوی اطلاعات مهم میباشد. این اعلامیه ممکن است حاوی اطلاعات مهم درباره فرم تقاضا و یا پوشش بیمه ای شما از طریق Premera Blue Cross باشد. به تاریخ های مهم در این اعلامیه توجه نمایید. شما ممکن است برای حفظ پوشش بیمه تان یا کمک در پرداخت هزینه های درمانی تان، به تاریخ های مشخصی برای انجام کارهای خاصی احتیاج داشته باشید. شما حق این را دارید که این اطلاعات و کمک را به زبان خود به طور رایگان دریافت نمایید. برای کسب اطلاعات با شماره 800-722-1471 (کلیران TTY تماس باشماره 800-842-5357) تماس برقرار نمایید.

**Polskie (Polish):**

To ogłoszenie może zawierać ważne informacje. To ogłoszenie może zawierać ważne informacje odnośnie Państwa wniosku lub zakresu świadczeń poprzez Premera Blue Cross. Prosimy zwrócić uwagę na kluczowe daty, które mogą być zawarte w tym ogłoszeniu aby nie przekroczyć terminów w przypadku utrzymania polisy ubezpieczeniowej lub pomocy związanej z kosztami. Macie Państwo prawo do bezpłatnej informacji we własnym języku. Zadzwońcie pod 800-722-1471 (TTY: 800-842-5357).

**Português (Portuguese):**

Este aviso contém informações importantes. Este aviso poderá conter informações importantes a respeito de sua aplicação ou cobertura por meio do Premera Blue Cross. Poderão existir datas importantes neste aviso. Talvez seja necessário que você tome providências dentro de determinados prazos para manter sua cobertura de saúde ou ajuda de custos. Você tem o direito de obter esta informação e ajuda em seu idioma e sem custos. Ligue para 800-722-1471 (TTY: 800-842-5357).

**Română (Romanian):**

Prezenta notificare conține informații importante. Această notificare poate conține informații importante privind cererea sau acoperirea asigurării dumneavoastră de sănătate prin Premera Blue Cross. Pot exista date cheie în această notificare. Este posibil să fie nevoie să acționați până la anumite termene limită pentru a vă menține acoperirea asigurării de sănătate sau asistența provizorie la costuri. Aveți dreptul de a obține gratuit aceste informații și ajutor în limba dumneavoastră. Sunați la 800-722-1471 (TTY: 800-842-5357).

**Русский (Russian):**

Настоящее уведомление содержит важную информацию. Это уведомление может содержать важную информацию о вашем заявлении или страховом покрытии через Premera Blue Cross. В настоящем уведомлении могут быть указаны ключевые даты. Вам, возможно, потребуется принять меры к определенным предельным срокам для сохранения страхового покрытия или помощи с расходами. Вы имеете право на бесплатное получение этой информации и помощь на вашем языке. Звоните по телефону 800-722-1471 (TTY: 800-842-5357).

**Fa'asamoa (Samoan):**

Atonu ua iai i lenei fa'asilasilaga ni fa'amatalaga e sili ona taua e tatau ona e malamalama i ai. O lenei fa'asilasilaga o se fesoasoani e fa'amatala atili i ai i le tulaga o le polokalame, Premera Blue Cross, ua e tau fia maua atu i ai. Fa'amolemole, ia e iloilo fa'alelei i aso fa'apitoa olo'o iai i lenei fa'asilasilaga taua. Masalo o le'a iai ni feau e tatau ona e faia ao le'i aulia le aso ua ta'ua i lenei fa'asilasilaga ina ia e iai pea ma maua fesoasoani mai ai i le polokalame a le Malo olo'o e iai i ai. Olo'o iai iate oe le aia tatau e maua atu i lenei fa'asilasilaga ma lenei fa'matalaga i legagana e te malamalama i ai aunoa ma se togiga tupe. Vili atu i le telefoni 800-722-1471 (TTY: 800-842-5357).

**Español (Spanish):**

Este Aviso contiene información importante. Es posible que este aviso contenga información importante acerca de su solicitud o cobertura a través de Premera Blue Cross. Es posible que haya fechas clave en este aviso. Es posible que deba tomar alguna medida antes de determinadas fechas para mantener su cobertura médica o ayuda con los costos. Usted tiene derecho a recibir esta información y ayuda en su idioma sin costo alguno. Llame al 800-722-1471 (TTY: 800-842-5357).

**Tagalog (Tagalog):**

Ang Paunawa na ito ay naglalaman ng mahalagang impormasyon tungkol sa iyong aplikasyon o pagsakop sa pamamagitan ng Premera Blue Cross. Maaaring may mga mahalagang petsa dito sa paunawa. Maaring mangailangan ka na magsagawa ng hakbang sa ilang mga itinakdang panahon upang mapanatili ang iyong pagsakop sa kalusugan o tulong na walang gastos. May karapatan ka na makakuha ng ganiitong impormasyon at tulong sa iyong wika ng walang gastos. Tumawag sa 800-722-1471 (TTY: 800-842-5357).

**ไทย (Thai):**

ประกาศนี้มีข้อมูลสำคัญ ประกาศนี้อาจมีข้อมูลที่สำคัญเกี่ยวกับกาการสมัครหรือขอบเขตประกันสุขภาพของคุณผ่าน Premera Blue Cross และอาจมีกำหนดการในประกาศนี้ คุณอาจจะต้องดำเนินการภายในกำหนดระยะเวลาที่แน่นอนเพื่อจะรักษาการประกันสุขภาพของคุณหรือการช่วยเหลือที่มีค่าใช้จ่าย คุณมีสิทธิที่จะได้รับข้อมูลและความช่วยเหลือในภาษาของคุณโดยไม่มีค่าใช้จ่าย โทร 800-722-1471 (TTY: 800-842-5357)

**Український (Ukrainian):**

Це повідомлення містить важливу інформацію. Це повідомлення може містити важливу інформацію про Ваше звернення щодо страховального покриття через Premera Blue Cross. Зверніть увагу на ключові дати, які можуть бути вказані у цьому повідомленні. Існує імовірність того, що Вам треба буде здійснити певні кроки у конкретні кінцеві строки для того, щоб зберегти Ваше медичне страхування або отримати фінансову допомогу. У Вас є право на отримання цієї інформації та допомоги безкоштовно на Вашій рідній мові. Дзвоніть за номером телефону 800-722-1471 (TTY: 800-842-5357).

**Tiếng Việt (Vietnamese):**

Thông báo này cung cấp thông tin quan trọng. Thông báo này có thông tin quan trọng về đơn xin tham gia hoặc hợp đồng bảo hiểm của quý vị qua chương trình Premera Blue Cross. Xin xem ngày quan trọng trong thông báo này. Quý vị có thể phải thực hiện theo thông báo đúng trong thời hạn để duy trì bảo hiểm sức khỏe hoặc được trợ giúp thêm về chi phí. Quý vị có quyền được biết thông tin này và được trợ giúp bằng ngôn ngữ của mình miễn phí. Xin gọi số 800-722-1471 (TTY: 800-842-5357).