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PHARMACY POLICY – 5.01.547

Medical Necessity Criteria and Dispensing Quantity Limits for Metallic Formulary Benefits

Effective Date:	May 1, 2025
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Replaces:	N/A

RELATED PHARMACY/MEDICAL POLICIES:

5.01.541	Medical Necessity Exception Criteria for Closed Formulary Benefits and Dispense as Written (DAW) Exception Reviews
5.01.605	Medical Necessity Criteria for Pharmacy Edits

Select a hyperlink below to be directed to that section.

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RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES | HISTORY

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Introduction

Prior authorization and step therapy are 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 prior authorization, step therapy, and quantity limits for specific drugs in the plan's formulary. This policy applies to the Individual/Small Group/Student ISHIP Metallic formulary (Rx plan M1, M2, and M4). Please refer to the member plan booklet or member ID card to determine if this policy applies.

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.

Drug	Medical Necessity
• **Entresto (sacubitril-valsartan)** • **Entresto Sprinkle (sacubitril-valsartan)**	**Entresto (sacubitril-valsartan) and Entresto Sprinkle (sacubitril-valsartan) may be considered medically necessary for the treatment of adults with heart failure when ALL the following criteria are met:** • The individual is aged 18 years or older **AND** • Has a diagnosis of chronic heart failure (NYHA Class II to IV) **AND** • Use is prescribed by or in consultation with a cardiologist or a cardiac care specialist **Entresto (sacubitril-valsartan) and Entresto Sprinkle (sacubitril-valsartan) may be considered medically necessary for pediatric heart failure when ALL the following criteria are met:** • The individual is aged 1 year or older **AND** • Has a diagnosis of symptomatic heart failure with systemic left ventricular systolic dysfunction **AND** • Use is prescribed by or in consultation with a cardiologist or a cardiac care specialist

Dispensing Quantity Limits

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

Drug	Dosage / Strength	Quantity Limit
Abiraterone	250 mg tablet	Limit: 120 tablets per 30 days
Abiraterone	500 mg tablet	Limit: 60 tablets per 30 days
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
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
Akynzeo	300-0.5 mg	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
Anastrozole	1 mg tablet	Limit: 30 tablets per 30 days
Androgel	25 mg (1%) packet	Limit: 30 packets per fill
Androgel	50 mg (1%) packet	Limit: 60 packets per fill
Androgel	12.5 mg (1%) gel pump	Limit: 300 actuations per fill
Androgel	20.25 mg (1.62%) packet	Limit: 30 packets per fill

Drug	Dosage / Strength	Quantity Limit
Androgel	40.5 mg (1.62%) packet	Limit: 60 packets per fill
Andogel	20.25 mg (1.62%) gel pump	Limit: 150 actuations per fill
Androderm	2 mg/24 hr. patch	Limit: 30 patches per fill
Androderm	4 mg/24 hr. patch	Limit: 30 patches per fill
Arnuity Ellipta	100 mcg (14 blisters)	Limit: 1 inhaler per fill
Arnuity Ellipta	100 mcg (30 blisters)	Limit: 1 inhaler per fill
Arnuity Ellipta	200 mcg (14 blisters)	Limit: 1 inhaler per fill
Arnuity Ellipta	200 mcg (30 blisters)	Limit: 1 inhaler per fill
Asmanex HFA	50 mcg/inh	Limit: 1 inhaler per fill
Asmanex HFA	100 mcg/inh	Limit: 1 inhaler per fill
Asmanex HFA	200 mcg/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
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
Axiron	30 mg (2%) per pump	Limit: 180 actuations per fill
Betaseron	0.3 mg vial	Limit: 14 prefilled diluent syringes per 30 days
Bicalutamide	50 mg tablet	Limit: 30 tablets per 30 days
Capecitabine	150 mg tablet	Limit: 84 tablets per 28 days
Capecitabine	500 mg tablet	Limit: 210 tablets per 28 days
Carbinoxamine	4 mg tablet	Limit: 240 tablets per 30 days
Carbinoxamine	6 mg tablet	Limit: 120 tablets per 30 days

Drug	Dosage / Strength	Quantity Limit
Carbinoxamine	4 mg/5 mL	Limit: 2 bottles per 30 days
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	20 mcg-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 syringes per 30 days
Desloratadine	2.5 mg orally disintegrating tablet	Limit: 30 tablets per 30 days
Desloratadine	5 mg orally disintegrating tablet	Limit: 30 tablets per 30 days
Desloratadine	5 mg tablet	Limit: 30 tablets 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	30/2 mg tablet	Limit: 30 tablets per fill
Duetact	30/4 mg tablet	Limit: 30 tablets per fill
Dulera	50 mcg/5mcg	Limit: 1 inhaler per fill
Dulera	100 mcg/5mcg	Limit: 1 inhaler per fill
Dulera	200 mcg/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	150 mg injection	Limit: 1 vial per fill
Emend	Bifold pack	Limit: 1 pack per fill
Emend	Trifold Pack, contains one 125 mg and two 80 mg capsules	Limit: 1 pack (package size 3) per fill

Drug	Dosage / Strength	Quantity Limit
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
Exemestane	25 mg tablet	Limit: 30 tablets per 30 days
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
Factive	320 mg tablet	Limit: 7 tablets per fill
Flovent Diskus	Powder 100 mcg (1 device = 60 doses)	Limit: 1 inhaler per fill
Flovent Diskus	Powder 250 mcg (1 device = 60 doses)	Limit: 4 inhalers per fill
Flovent Diskus	Powder 50 mcg (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
Flutamide	125 mg capsule	Limit: 180 capsules per 30 days
Fortesta	10 mg (2%) gel pump	Limit: 120 actuations per fill
Granisetron	1 mg tablet	Limit: 6 tablets per fill
Imatinib	100 mg tablet	Limit: 90 tablets per 30 days
Imatinib	400 mg tablet	Limit: 60 tablets per 30 days
Incruse Ellipta	62.5 mcg (7 blister)	Limit: 1 inhaler per fill
Incruse Ellipta	62.5 mcg (30 blister)	Limit: 1 inhaler per fill
Ipratropium/albuterol	3 ml vial	Limit: 180 vials per fill
Kesimpta	20 mg pen	Limit: 1 pen per 28 days
Letrozole	2.5 mg tablet	Limit: 30 tablets per 30 days
Mayzent	0.25 mg tablet	Limit: 120 tablets per 30 days
Mayzent	2 mg tablet	Limit: 30 tablets per 30 days
Megestrol	20 mg tablet	Limit: 480 tablets per 30 days

Drug	Dosage / Strength	Quantity Limit
Megestrol	40 mg tablet	Limit: 240 tablets per 30 days
Megestrol	40 mg/ml suspension	Limit: 2 bottles per 30 days
Megestrol	125 mg/ml suspension	Limit: 1 bottle per 30 days
Melphalan	2 mg tablet	Limit: 63 tablets per 21 days
Menostar	14 mcg/day patch	Limit: 4 patches per 30 days
Mercaptopurine	50 mg tablet	Limit: 300 tablets per 30 days
Minitran	0.1 mg/hr patch	Limit: 30 patches per 30 days
Minitran	0.2 mg/hr patch	Limit: 30 patches per 30 days
Minitran	0.4 mg/hr patch	Limit: 60 patches per 30 days
Minitran	0.6 mg/hr patch	Limit: 30 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
Natesto	5.5 mg per pump	Limit: 180 actuations per fill
Nilutamide	150 mg tablet	Limit: 60 tablets per 30 days
Nitro-Dur	0.1 mg/hr patch	Limit: 30 patches per 30 days
Nitro-Dur	0.2 mg/hr patch	Limit: 30 patches per 30 days
Nitro-Dur	0.3 mg/hr patch	Limit: 30 patches per 30 days
Nitro-Dur	0.4 mg/hr patch	Limit: 30 patches per 30 days
Nitro-Dur	0.6 mg/hr patch	Limit: 30 patches per 30 days
Nitro-Dur	0.8 mg/hr patch	Limit: 30 patches per 30 days
Plegridy	125 mcg/0.5ml pen	Limit: 2 pens per 30 days
Plegridy	63/94 mcg starter pack	Limit: 1 starter pack per 365 days
Pulmicort Flexhaler	90 mcg/actuation	Limit: 1 inhaler per fill
Pulmicort Flexhaler	180 mcg/actuation	Limit: 2 inhaler per fill
Pulmicort Respules (budesonide)	0.25 mg/2 mL	Limit: 60 respules per fill
Pulmicort Respules budesonide)	0.5 mg/2 mL	Limit: 60 respules per fill
Pulmicort Respules budesonide)	1 mg/2 mL	Limit: 30 respules per fill
Qvar HFA	40 mcg	Limit: 2 inhalers per fill

Drug	Dosage / Strength	Quantity Limit
Qvar HFA	80 mcg	Limit: 3 inhalers per fill
Rebif	22 mcg syringe	Limit: 12 syringes per 30 days
Rebif	44 mcg 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
Restasis	0.4 mL vial (0.5 mg/mL)	Limit: 60 vials per 30 days
Sancuso	3.1 mg/24-hour patch	Limit: 1 patch per fill
Sivextro	200 mg tablet	Limit: 6 tablets 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	4 gm inhaler (28 spray)	Limit: 1 inhaler per fill
Spiriva Respimat	4 gm inhaler (60 spray)	Limit: 1 inhaler per fill
Striant	30 mg buccal tablets	Limit: 60 buccal tablets 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
Tamoxifen	10 mg tablet	Limit: 60 tablets per 30 days
Tamoxifen	20 mg tablet	Limit: 60 tablets per 30 days
Testim	50 mg (1%) gel	Limit: 60 tubes per fill
Testosterone	50 mg (1%) packet	Limit: 60 packets per fill
Testosterone	12.5 mg (1%) gel pump	Limit: 300 actuations per fill
Testosterone	10 mg (2%) gel pump	Limit: 120 actuations per fill
Tudorza Pressair	400 mcg inhaler	Limit: 1 inhaler per fill

Drug	Dosage / Strength	Quantity Limit
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
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
Vogelxo	50 mg (1%) gel	Limit: 60 tubes per fill
Vogelxo	50 mg (1%) gel packet	Limit: 60 packets per fill
Vogelxo	12.5 mg (1%) per pump	Limit: 300 actuations per fill
Xiidra	0.2 mL single-use container (50 mg/mL)	Limit: 60 containers 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)	4 mg/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	8.6 mg/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	150 mg/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**.

Drug	Dosage/Strength	Quantity Limit
Abacavir	20 mg/ml	Limit: 60 mL per 30 days
Abacavir	300 mg	Limit: 60 Tablets per 30 days
Abacavir-Lamivudine	600-300 mg	Limit: 30 Tablets per 30 days
Aptivus	100 mg/ml	Limit: 5700 mL per 30 days
Aptivus	250 mg	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	100-300 mg	Limit: 30 Tablets per 30 days
Didanosine dr	All	Limit: 30 Capsules per 30 days
Dovato	All	Limit: 30 Tablets per 30 days
Edurant	All	Limit: 30 Tablets per 30 days
Efavirenz	All	Limit: 30 Tablets/Capsules per 30 days
Emtriva	10 mg/mL	Limit: 20,400 mL per 30 days
Emtriva	200 mg	Limit: 30 Capsules per 30 days
Epivir	10 mg/mL	Limit: 900 mL per 30 days
Epivir	150 mg	Limit: 60 Tablets per 30 days
Epivir	300 mg	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

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

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

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for drugs listed in this policy may be approved up to 12 months**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for drugs listed in this policy may be approved up to 12 months**

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 individuals; 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 US. 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 individual-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.

Evidence Review

Entresto (valsartan/sacubitril)

Entresto (valsartan/sacubitril or LCZ696) was granted fast track approval by the FDA for heart failure with reduced ejection fraction (HFrEF) based on the results of the PARADIGM HF trial, which randomized 8,441 individuals to receive LCZ696 200mg twice daily (n=4187) or enalapril 10mg twice daily (n=4212). LCZ696 was superior to enalapril at reducing the composite endpoint of cardiovascular death and first heart failure hospitalization (HR 0.80, 95% CI 0.73-0.87, p<0.001). When assessed individually, both components of the composite occurred in a lower proportion of individuals in the LCZ696 arm (p<0.001 for both). All-cause mortality occurred in 17% of the LCZ696 group compared to 19.8% in the enalapril arm (p<0.001). A 29% reduction in recurrent hospitalizations was seen with LCZ696 (p=0.001). Due to the statistically significant reduction in the primary endpoint, the study was prematurely stopped. The phase II PARAMOUNT trial has shown beneficial results with LCZ696 compared to valsartan in individuals who have heart failure with preserved ejection fraction. LCZ696 significantly reduced NT-proBNP at 12 weeks (ratio of change LCZ696/valsartan 0.77, 95% CI 0.64-0.92, p=0.005).

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 individual. 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. Individuals 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.[1]

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 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.[2] 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.[3]

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.[4-6]

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.[7] 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.

2019 Update

Review of current FDA labeling. Added Leukine indication for exposure to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome).

2020 Update

Reviewed prescribing information for Actimmune (interferon gamma-1b), Leukine (sargramostim), Jakafi (ruxolitinib), and Ilaris (canakinumab). Added a new indication for Jakafi for the treatment of steroid-refractory acute graft-versus-host disease in adult and pediatric individuals 12 years and older. Updated age of coverage for other Jakafi indications to adults 18 years of age or older. Reviewed formulary status for medications in Step Therapy Protocol. Changed from one to two requirements for first step therapy agents unless specified otherwise. Removed from targeting Toziaz, Vesicare, Epiduo forte, Tazorac, Welchol and Ranexa as removed from formulary. Added generic solifenacin as a first step therapy agent for overactive bladder.

2021 Update

Reviewed product availability and formulary status for all drugs listed in step-therapy table. Removed Anzemet tablets (dolasetron), Cesamet (nabilone), and Oxecta (oxycodone) from step-therapy table as products have been discontinued by manufacturer. Removed Butrans (buprenorphine transdermal), Nucynta (tapentadol), and Ventolin HFA (albuterol) from step-therapy table as products are non-formulary.

2022 Update

Reviewed product availability and formulary status for all drugs listed in step-therapy table. Removed Bystolic (nebivolol) as product is non-formulary due to the availability of generic nebivolol which is formulary.

2023 Update

Reviewed product availability and formulary status for all drugs listed in step-therapy table. Removed Aerospan from the quantity limit as it has been discontinued by the manufacturer.

2024 Update

Reviewed product availability and formulary status for all drugs listed in step-therapy table. Added Alrex (loteprednol) eye drops to the ophthalmic corticosteroids step-therapy table. Removed Myrbetriq (mirabegron) from the step-therapy table as it has been added to 5.01.605 Medical Necessity Criteria for Pharmacy Edits. Added coverage criteria for Entresto (sacubitril-valsartan) and Entresto Sprinkle (sacubitril-valsartan). Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

2025 Update

Reviewed product availability and formulary status for all drugs. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12

months. Updated the policy title from "Medical Necessity Criteria and Dispensing Quantity Limits for Exchange Formulary Benefits" to "Medical Necessity Criteria and Dispensing Quantity Limits for Metallic Formulary Benefits." Removed the following drugs from the step therapy protocol: Alrex, buprenorphine patch, carbinoxamine, desloratadine, Emsam, Factive, Inveltys, Lotomax, Minitran, Nitro-Dur, Nucynta ER, ranolazine extended-release, Suprep, tazarotene, and U-Cort.

References

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6. Law MR, Lu CY, Soumerai SB, et al. Impact of prior authorization on the use and costs of lipid-lowering medications among Michigan and Indiana dual enrollees in Medicaid and Medicare: results of a longitudinal, population-based study. Clin Ther. 2011;33(1):135-44.
7. 21 CFR 201.5: Labeling Requirements for Prescription Drugs. Adequate Directions for Use. Available at **http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=201** Accessed February 11, 2025.
8. Entresto (sacubitril-valsartan). Prescribing Information. Novartis Pharmaceuticals Corporation. East Hanover, NJ. Revised April 2024.

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.

Date	Comments
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.
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

Date	Comments
	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 Review, 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 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.
02/01/19	Interim Review, approved January 4, 2019. Added new medication Inveltys to ophthalmic corticosteroids.
05/01/19	Annual Review, approved April 18, 2019. Added buprenorphine patch as second step drug for pain. Added ranolazine extended-release as second step drug for angina. Added new indication to Leukine (sargramostim). Updated Epivir (lamivudine) quantity limit.

Date	Comments
06/01/19	Interim Review, approved May 23, 2019. Added dispensing quantity limits for Androgel, Androderm, Axiron, Fortesta, Natesto, Striant, Testim, Testosterone and Vogelxo. Added Dovato to the antiretroviral quantity limits.
08/01/19	Interim Review, approved July 25, 2019. Added Symtuza to the antiretroviral quantity limits.
10/01/19	Interim Review, approved September 5, 2019. Added Dexilant (dexlansoprazole) as a drug that requires step therapy. Added generic loteprednol to the list of first step agents for ophthalmic corticosteroids.
02/01/20	Interim Review, approved January 9, 2020. Removed Brilinta from step therapy protocol.
04/01/20	Annual Review, approved March 3, 2020. Added new indication to Jakafi for steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. Updated age of coverage for other Jakafi indications to adults 18 years of age or older. Changed from one to two requirements for first step therapy agents. Removed from targeting for Step Therapy Protocol Toviaz, Vesicare, Epiduo forte, Tazorac, Welchol and Ranexa. Added generic solifenacin as a first step therapy agent for overactive bladder.
05/01/20	Interim Review, approved April 23, 2020. Added Asmanex 50 mcg/inhaler and Dulera 50 mcg/5 mcg inhaler to the quantity limits.
08/01/20	Interim Review, approved July 23, 2020. Added new indication to Ilaris for AOSD and updated age of coverage for SJIA to patients aged 2 years and older. Added Tivicay PD to the quantity limits.
10/01/20	Interim Review, approved September 17, 2020. Updated step-therapy requirement on Ventolin HFA requiring trial and failure of generic albuterol HFA prior to Ventolin HFA.
11/01/20	Interim Review, approved October 22, 2020. Moved Jakafi to Policy 5.01.540 Miscellaneous Oncology Drugs. Moved Proton Pump Inhibitors to Policy 5.01.605 Medical Necessity Criteria for Pharmacy Edits. Updated Copaxone 40 mg prefilled syringe quantity limit to 12 syringes per 30 days.
02/01/21	Interim Review, approved January 21, 2021. Leukine removed from Policy as added to Policy 5.01.540 Miscellaneous Oncology Drugs effective 12/3/20. Ilaris removed from Policy as added to Policy 5.01.564 Pharmacotherapy of Miscellaneous Autoimmune Diseases effective 1/1/21. Cayston removed from Policy as added to Policy 5.01.605 Medical Necessity Criteria for Pharmacy Edits effective 12/1/20. Added Sivextro to the dispensing quantity limits.
04/01/21	Interim Review, approved March 23, 2021. Actimmune removed from Policy as added to Policy 5.01.605 Medical Necessity Criteria for Pharmacy Edits effective 3/3/21. Added abiraterone, anastrozole, bicalutamide, capecitabine, exemestane, flutamide, imatinib, letrozole, Mayzent, megestrol, melphalan, mercaptopurine, nilutamide, and tamoxifen to the quantity limits.

Date	Comments
05/01/21	Annual Review, approved April 22, 2021. Added step-therapy requirement and quantity limits to carbinoxamine and desloratadine. Removed Anzemet and Cesamet from step-therapy and quantity limit tables as products have been discontinued by manufacturer. Removed Oxecta from step-therapy table as product has been discontinued by manufacturer. Removed Butrans, Nucynta, and Ventolin HFA from step-therapy table. Added a quantity limit to Factive, Minitran, Nitro-Dur, Restasis, and Xiidra.
10/01/21	Interim Review, approved September 23, 2021. Added a quantity limit to Kesimpta.
03/01/22	Interim Review, approved February 7, 2022. Added a note that generic tazarotene is covered for the treatment of plaque psoriasis and that use of the first step agents is not required for plaque psoriasis. Removed Descovy and Truvada from the quantity limit as the drugs are now reviewed under Policy 5.01.588 Pharmacologic Treatment of HIV/AIDS.
11/01/22	Annual Review, approved October 10, 2022. Removed Bystolic (nebivolol) from the step-therapy table as product is non-formulary. Changed the wording from "patient" to "individual" throughout the policy for standardization.
09/01/23	Annual Review, approved August 21, 2023. Reviewed product availability and formulary status for all drugs listed in step-therapy table. Removed Aerospan from the quantity limit as it has been discontinued by the manufacturer.
04/01/24	Annual Review, approved March 25, 2024. Added Alrex (loteprednol) eye drops to the ophthalmic corticosteroids step-therapy table. Removed Myrbetriq (mirabegron) from the step-therapy table as it has been added to 5.01.605 Medical Necessity Criteria for Pharmacy Edits.
01/01/25	Interim Review, approved December 23, 2024. Entresto (sacubitril-valsartan) moved from Policy 5.01.605 to 5.01.547 with no changes to coverage criteria. Clarified that Entresto policy criteria includes Entresto Sprinkle (sacubitril-valsartan). Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.
03/01/25	Annual Review, approved February 24, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months.
05/01/25	Interim Review, approved April 8, 2025. Updated the policy title from “Medical Necessity Criteria and Dispensing Quantity Limits for Exchange Formulary Benefits” to “Medical Necessity Criteria and Dispensing Quantity Limits for Metallic Formulary Benefits.” Removed the following drugs from the step therapy protocol: Alrex, buprenorphine patch, carbinoxamine, desloratadine, Emsam, Factive, Inveltys, Lotomax, Minitran, Nitro-Dur, Nucynta ER, ranolazine extended-release, Suprep, tazarotene, and U-Cort.

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.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.