Drug and Biologic Coverage Policy

Effective Date **2/1/2024**
Next Review Date **2/1/2025**
Coverage Policy Number **1201**

Quantity Limitations

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses Quantity Limitation requirements and exceptions, in accordance to generally accepted drug and biologic dose, frequency, supply, and duration of therapy medical practice standards supported by FDA product information (Label), standard medical reference compendia, or evidence-based literature.

Coverage Policy Statement

Drugs and Biologics are considered medically necessary to exceed generally accepted quantity limitations, in accordance with benefit plan specifications, when EITHER of the following criteria have been met:

- **Dosage, frequency, site of administration, and duration of therapy is supported by the FDA product information (Label)**

- **Dosage, frequency, site of administration, and duration of therapy should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy as applicable**

Supportive evidence examples include, but are not limited: FDA product information (Label), Standard medical reference compendia [for example, American Hospital Formulary Service-Drug Information (AHFS-DI)].

Product-specific additional exceptions are noted in table below. Any other exception is considered not medically necessary.

Product-specific Quantity Limitations / Exceptions

Product	Quantity Limit / Exception Criteria
Aciphex (rabeprazole)	**Quantity Limit:** • 5 mg: 4 sprinkle caps per day • 10 mg: 2 sprinkle caps per day • 20 mg: 1 tablet per day **Additional exception to the Quantity Limit:** 1. For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 60 mg and 120 mg per day may be approved. 2. For a documented diagnosis of *Helicobacter pylori*: Additional quantities for doses up to 80 mg per day up to 14 days may be approved.
Adalimumab (Abrilada, adalimumab-adaz, adalimumab - adbm, adalimumab-fkjp, Amjevita, Cyltezo, Hadlima, Humira, Humira CF, Hulio, Hyrimoz [manufactured by Sandoz/Novartis]**, Idacio, Yuflyma, Yusimry)**	**Quantity Limit:** • 2 pens or pre-filled syringes per 28 days • Starter Kit: 1 kit per 365 days **Additional exception to the Quantity Limit:** 1. For a documented diagnosis of Rheumatoid Arthritis, Crohn's Disease, or Hidradenitis Suppurativa: Additional quantities up to 4 pens or pre-filled syringes per 28 days may be approved 2. Induction for Plaque Psoriasis, Uveitis, Crohn's Disease, Ulcerative Colitis, Hidradenitis Suppurativa: Quantity limit to FDA recommended dose
Budesonide / Formoterol 80/4.5 mcg and 160/4.5 mcg inhalation aerosol (generic for Symbicort)	**Quantity Limit:** • 1 inhaler per month **Additional exception to the Quantity Limit:** If the individual has asthma and is using budesonide / formoterol as a reliever therapy, approve up to 2 inhalers per dispensing.
Budesonide nebulizer suspension	**Quantity Limit:** • 0.25 mg/2ml and 0.5 mg/2mL: 60 respules • 1 mg/2mL: 30 respules **Additional exception to the Quantity Limit:** Budesonide Inhalation Suspension (Pulmicort Respules, generic) 0.25 mg/2 mL and 0.5 mg/2 mL respules No overrides recommended. Budesonide Inhalation Suspension (Pulmicort Respules, generic) 1 mg/2 mL respules

	1. If the individual has esophageal eosinophilia/eosinophilic esophagitis, approve up to 60 respules per dispensing. 2. If the individual is ≥ 11 years of age and according to the prescriber requires a dose greater than 1 mg per day, approve up to 120 respules per dispensing. 3. If the individual is ≥ 18 years of age and is experiencing a chronic obstructive pulmonary disease exacerbation, approve a one-time override for up to 240 respules.
Cimzia (certolizumab pegol)	**Quantity Limit:** • 2 vials or pre-filled syringes per 28 days • Starter Kit: 1 kit per 365 days **<u>Additional exception to the Quantity Limit:</u>** 1. For a documented diagnosis of Plaque Psoriasis: Additional quantities up to 4 syringes per 28 days may be approved 2. For induction for Crohn's Disease, Rheumatoid Arthritis, Ankylosing Spondylitis, Psoriatic Arthritis: Quantity limit to FDA recommended dose
Cosentyx (secukinumab)	**Quantity Limit:** • Carton of two 150 mg/mL (300 mg dose) per 28 days • Carton of one 150mg/ml (150mg dose) per 28 days **<u>Additional exception to the Quantity Limit:</u>** For induction for Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis: Quantity limit to FDA recommended dose
Esomeprazole strontium	**Quantity Limit:** • 49.3 mg: 1 capsule per day **<u>Additional exception to the Quantity Limit:</u>** For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 89.2 mg and 267.6 mg (equivalent to 240 mg of esomeprazole magnesium) per day may be approved. The FDA recommended dose per day for treatment of Helicobacter pylori does not exceed the quantity limits above.
Enbrel (etanercept)	**Quantity Limit:** • 25mg: 8 vials or pre-filled syringes per 28 days • 50mg: 4 Sureclicks, mini cartridges, or pre-filled syringes per 28 days **<u>Additional exception to the Quantity Limit:</u>** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Ilumya (tildrakizumab-asmn)	**Quantity Limit:** • 1 pre-filled syringe per 84 days **<u>Additional exception to the Quantity Limit:</u>** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Kineret (anakinra)	**Quantity Limit:** • 28 pre-filled syringes per 28 days **<u>Additional exception to the Quantity Limit:</u>** For the treatment of cryopyrin-associated periodic syndromes (CAPS) or deficiency of interleukin-1 receptor antagonist (DIRA): Additional quantities sufficient to allow for dosing of up to 8 mg per kg per day may be approved
Livtencity (maribavir)	**Quantity Limit:** • 4 tablets per day

	Additional exception to the Quantity Limit: 224 tablets as a 28-day supply, when the following criteria are met: If an individual is taking carbamazepine concomitantly with Livtencity 336 tablets as a 28-day supply, when the following criteria are met: If an individual is taking phenytoin or phenobarbital concomitantly with Livtencity
Nexium (esomeprazole magnesium)	**Quantity Limit:** • 2.5 mg: 16 packets per day • 5 mg: 8 packets per day • 10 mg: 4 packets per day • 20 mg: 2 capsules or packets per day • 40 mg: 1 capsule or packet per day **Additional exception to the Quantity Limit:** 1. For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 80 mg and 240 mg per day may be approved. 2. For a documented diagnosis of *Helicobacter pylori*: Additional quantities for doses up to 80 mg per day up to 14 days may be approved.
Oxbryta (voxelotor) 500 mg tablets	**Quantity Limit:** • 3 tablets per day **Additional exception to the Quantity Limit:** Up to 150 tablets per dispensing, when the following criteria are met: If the individual is ≥ 12 years of age OR is 4 to 11 years of age and weighs ≥ 40 kg and is taking Oxbryta with a moderate or strong cytochrome P450 (CYP)3A4 inducer (for example, carbamazepine, enzalutamide, apalutamide, mitotane, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, etravirine, phenobarbital, primidone)
Oxbryta (voxelotor) 300 mg tablets	**Quantity Limit:** • 90 count bottle: 3 tablets per day • 60 count bottle: 2 tablets per day **Additional exception to the Quantity Limit:** Up to 240 tablets per dispensing when the following criteria are met: If the individual is 4 to 11 years of age and weighs ≥ 40 kg and is taking Oxbryta with a moderate or strong cytochrome P450 (CYP)3A4 inducer (for example, carbamazepine, enzalutamide, apalutamide, mitotane, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, etravirine, phenobarbital, primidone)
Oxbryta (voxelotor) 300 mg tablets for oral suspension	**Quantity Limit:** • 90 count bottle: 5 tablets per day • 60 count bottle: 5 tablets per day **Additional exception to the Quantity Limit:** Up to 240 tablets for oral suspension per dispensing when the following criteria are met: If the individual is 4 to 11 years of age and weighs ≥ 40 kg and is taking Oxbryta with a moderate or strong cytochrome P450 (CYP)3A4 inducer (for example, carbamazepine, enzalutamide, apalutamide, mitotane, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, etravirine, phenobarbital, primidone)
Prevacid, Heartburn Relief 24 Hour (lansoprazole)	**Quantity Limit:** • 15 mg: 2 capsules or solutabs per day • 30 mg: 1 capsule or solutab per day **Additional exception to the Quantity Limit:**

	1. For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 60 mg and 180 mg per day may be approved. 2. For a documented diagnosis of *Helicobacter pylori*: Additional quantities for doses up to 90 mg per day up to 14 days may be approved.
Prilosec (omeprazole magnesium)	**Quantity Limit:** • 2.5 mg: 16 packets per day • 10 mg: 4 capsules or packets per day • 20 mg: 2 capsules per day • 40 mg: 1 capsule per day **Additional exception to the Quantity Limit:** 1. For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 60 mg and 360 mg per day may be approved. 2. For a documented diagnosis of *Helicobacter pylori*: Additional quantities for doses up to 80 mg per day up to 14 days may be approved.
ProAir Digihaler, ProAir HFA, ProAir Respiclick (albuterol sulfate)	**Quantity Limit:** • 1 inhaler per 30 days **Additional exception to the Quantity Limit:** For individuals with Asthma/Reactive Airway Disease, or Chronic Obstructive Pulmonary Disease (COPD), AND the prescriber attests that the individual needs an additional inhaler per 30 days: Approve a one-time override of one inhaler based on the quantities as noted above.
Protonix (pantoprazole)	**Quantity Limit:** • 20 mg: 2 tablets per day • 40 mg: 1 tablet or packet per day **Additional exception to the Quantity Limit:** 1. For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 80 mg and 240 mg per day may be approved. 2. For a documented diagnosis of *Helicobacter pylori*: Additional quantities for doses up to 160 mg per day up to 14 days may be approved.
Proventil HFA (albuterol sulfate)	**Quantity Limit:** • 1 inhaler per 30 days **Additional exception to the Quantity Limit:** For individuals with Asthma/Reactive Airway Disease, or Chronic Obstructive Pulmonary Disease (COPD), AND the prescriber attests that the individual needs an additional inhaler per 30 days: Approve a one-time override of one inhaler based on the quantities as noted above.
Skyrizi (risankizumab-rzaa)	**Quantity Limit:** • 75 mg: 1 kit per 84 days = 2 syringes • 150 mg: 1 syringe/pen per 84 days **Additional exception to the Quantity Limit:** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Siliq (brodalumab)	**Quantity limit:** • 2 syringes per 28 days **Additional exception to the Quantity Limit:** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Simponi	**Quantity Limit:**

(golimumab)	• 50mg: 1 pen or pre-filled syringe per 28 days • 100mg: 1 pen or pre-filled syringe per 28 days **Additional exception to the Quantity Limit:** For induction for Ulcerative Colitis: Quantity limit to FDA recommended dose
Stelara (ustekinumab)	**Quantity Limit:** • 1 pre-filled syringe per 84 days **Additional exception to the Quantity Limit:** For a documented diagnosis of Crohn's Disease or Ulcerative Colitis: Additional quantities up to 1 pre-filled syringe per 56 days may be approved For induction for Plaque Psoriasis, Psoriatic Arthritis: Quantity limit to FDA recommended dose
Symbicort (budesonide / formoterol inhalation aerosol)	**Quantity Limit:** • 1 inhaler per month **Additional exception to the Quantity Limit:** If the individual has asthma and is using budesonide / formoterol as a reliever therapy, approve up to 2 inhalers per dispensing.
Taltz (ixekizumab)	**Quantity Limit:** • 1 auto-injector per 28 days **Additional exception to the Quantity Limit:** For induction for Plaque Psoriasis, Psoriatic Arthritis: Quantity limit to FDA recommended dose
Tremfya (guselkumab)	**Quantity Limit:** • 1 pre-filled syringe per 56 days **Additional exception to the Quantity Limit:** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Ventolin HFA (albuterol sulfate)	**Quantity Limit:** • 1 inhaler per 30 days **Additional exception to the Quantity Limit:** For individuals with Asthma/Reactive Airway Disease, or Chronic Obstructive Pulmonary Disease (COPD), AND the prescriber attests that the individual needs an additional inhaler per 30 days: Approve a one-time override of one inhaler based on the quantities as noted above.
Vtama (tapinarof cream)	**Quantity Limit:** 1 tube (60 grams) per 30 days **Additional exception to the Quantity Limit:** If an individual needs to treat greater than 8% of their body surface area, approve the requested quantity, not to exceed 120 grams (2 tubes) per 30 days
Xifaxan 550 mg (rifaximin)	**Quantity Limit:** 550 mg: 42 tabs per 14 days, 126 tabs per 365 days **Additional exception to the Quantity Limit:** For Hepatic Encephalopathy: Quantity limit does not apply
Xopenex HFA (levalbuterol)	**Quantity Limit:** • 1 inhaler per 30 days **Additional exception to the Quantity Limit:**

	For individuals with Asthma/Reactive Airway Disease, or Chronic Obstructive Pulmonary Disease (COPD), AND the prescriber attests that the individual needs an additional inhaler per 30 days: Approve a one-time override of one inhaler based on the quantities as noted above.
Zoryve (roflumilast cream)	**Quantity Limit:** **1 tube (60 gram tube) per 30 day** **Additional exception to the Quantity Limit** If an individual needs to treat greater than 8% of their body surface area, approve the requested quantity, not to exceed 120 grams (2 tubes) per 30 days

General Background

Commercial medical plans (employer group and individual and family plans) may be subject to quantity limitations associated with the quantity submitted where the quantity limitations are set in accordance to the published FDA recommended dosing of a product, published clinical compendia, and in accord with CMS (Center for Medicare Medicaid) published allowances. Claims in excess of these standards can be considered medically necessary as long as not contraindicated by the FDA and supported with published clinical information in drug compendia or peer-reviewed studies showing both safety and efficacy at the proposed dose or quantity of use for a specific indication.

The Institute of Medicine (IOM) estimates that at least 1.5 million preventable adverse drug events occur within the healthcare system each year. The costs of these preventable adverse drug events have been estimated to exceed $4 billion annually.

Certain preventable adverse drug events relate to improper medication use. The Food and Drug Administration (FDA) launched the Safe Use Initiative to avoid improper medication use. Improper medication use increases the risk of harm from medication, often resulting in hundreds of thousands of injuries or deaths each year. Many of these injuries and adverse events could have been prevented with currently available knowledge. Frequency limitations are placed on pharmaceutical products to assure appropriate dosing and safe medication use as published in the FDA Product Information or “Label”.

Standard Medical Reference Compendia
Standard medical reference compendia utilized to establish frequency limitations include, but not limited to: American Hospital Formulary Service-Drug Information (AHFS), Truven Health Analytics Micromedex Drugpoints, and Wolters Kluwer Facts & Comparisons eAnswers.

References

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