



Drug and Biologic Coverage Policy

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Coverage Policy Number 1201

Quantity Limitations

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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 |
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| Aciphex (rabeprazole) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 5 mg: 4 sprinkle caps per day 10 mg: 2 sprinkle caps per day 20 mg: 1 tablet per day <p>Additional exception to the Quantity Limit:</p> <ol style="list-style-type: none"> For a documented diagnosis of Zollinger-Ellison syndrome: Additional quantities for doses between 60 mg and 120 mg per day may be approved. For a documented diagnosis of <i>Helicobacter pylori</i>: Additional quantities for doses up to 80 mg per day up to 14 days may be approved. |
| Adalimumab (Abrilada, adalimumab-aaty, adalimumab-adaz, adalimumab - adbm, adalimumab-fkjp, adalimumab-ryvk, Amjevita, Cyltezo, Hadlima, Humira [by AbbVie], Humira CF [by AbbVie], Hulio, Hyrimoz [by Sandoz/Novartis], Idacio, Simlandi, Yuflyma, Yusimry) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 2 pens or pre-filled syringes per 28 days Starter Kit: 1 kit per 365 days <p>Additional exception to the Quantity Limit:</p> <ol style="list-style-type: none"> 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 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) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 1 inhaler per month <p>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.</p> |
| Budesonide nebulizer suspension | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 0.25 mg/2ml and 0.5 mg/2mL: 60 respules 1 mg/2mL: 30 respules <p>Additional exception to the Quantity Limit: <u>Budesonide Inhalation Suspension (Pulmicort Respules, generic) 0.25 mg/2 mL and 0.5 mg/2 mL respules</u> No overrides recommended.</p> <p><u>Budesonide Inhalation Suspension (Pulmicort Respules, generic) 1 mg/2 mL respules</u></p> |

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| | <ol style="list-style-type: none"> 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) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 2 vials or pre-filled syringes per 28 days • Starter Kit: 1 kit per 365 days <p><u>Additional exception to the Quantity Limit:</u></p> <ol style="list-style-type: none"> 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) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • Carton of two 150 mg/mL (300 mg dose) per 28 days • Carton of one 150mg/ml (150mg dose) per 28 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis: Quantity limit to FDA recommended dose</p> |
| Esomeprazole strontium | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 49.3 mg: 1 capsule per day <p><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.</p> <p>The FDA recommended dose per day for treatment of Helicobacter pylori does not exceed the quantity limits above.</p> |
| Enbrel (etanercept) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 25mg: 8 vials or pre-filled syringes per 28 days • 50mg: 4 Sureclicks, mini cartridges, or pre-filled syringes per 28 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose</p> |
| Ilumya (tildrakizumab-asmn) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 pre-filled syringe per 84 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose</p> |
| Kineret (anakinra) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 28 pre-filled syringes per 28 days <p><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</p> |
| Livtency (maribavir) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 4 tablets per day |

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| | <p><u>Additional exception to the Quantity Limit:</u> 224 tablets as a 28-day supply, when the following criteria are met: If an individual is taking carbamazepine concomitantly with Livtency</p> <p>336 tablets as a 28-day supply, when the following criteria are met: If an individual is taking phenytoin or phenobarbital concomitantly with Livtency</p> |
| <p>Nexium (esomeprazole magnesium)</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 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 <p><u>Additional exception to the Quantity Limit:</u></p> <ol style="list-style-type: none"> 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 <i>Helicobacter pylori</i>: Additional quantities for doses up to 80 mg per day up to 14 days may be approved. |
| <p>Oxbryta (voxelotor) 500 mg tablets</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 3 tablets per day <p><u>Additional exception to the Quantity Limit:</u> 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)</p> |
| <p>Oxbryta (voxelotor) 300 mg tablets</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 90 count bottle: 3 tablets per day • 60 count bottle: 2 tablets per day <p><u>Additional exception to the Quantity Limit:</u> 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)</p> |
| <p>Oxbryta (voxelotor) 300 mg tablets for oral suspension</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 90 count bottle: 5 tablets per day • 60 count bottle: 5 tablets per day <p><u>Additional exception to the Quantity Limit:</u> 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)</p> |
| <p>Paxlovid (Nirmatrelvir and Ritonavir)</p> | <p><u>Quantity Limit</u></p> <ul style="list-style-type: none"> • One course of treatment (1 carton of 5 blister cards) every 120 days <p><u>Additional exception to the Quantity Limit:</u></p> |

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| | <p>A one-time override for a second course of treatment (either one 30 tablet carton or one 20 tablet carton) is available if the patient meets BOTH of the following (A <u>and</u> B):</p> <p>A) Patient has a repeat diagnosis of COVID-19; AND <u>Note:</u> This is a second diagnosis unrelated to the initial diagnosis of COVID-19 which was treated with Paxlovid.</p> <p>B) At least 90 days have elapsed since completion of the initial course of Paxlovid for treatment of COVID-19.</p> |
| <p>Prevacid, Heartburn Relief 24 Hour (lansoprazole)</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 15 mg: 2 capsules or solutabs per day • 30 mg: 1 capsule or solutab per day <p><u>Additional exception to the Quantity Limit:</u></p> <ol style="list-style-type: none"> 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 <i>Helicobacter pylori</i>: Additional quantities for doses up to 90 mg per day up to 14 days may be approved. |
| <p>Prilosec (omeprazole magnesium)</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 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 <p><u>Additional exception to the Quantity Limit:</u></p> <ol style="list-style-type: none"> 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 <i>Helicobacter pylori</i>: Additional quantities for doses up to 80 mg per day up to 14 days may be approved. |
| <p>ProAir Digihaler, ProAir HFA, ProAir Respiclick (albuterol sulfate)</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 inhaler per 30 days <p><u>Additional exception to the Quantity Limit:</u> 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.</p> |
| <p>Protonix (pantoprazole)</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 20 mg: 2 tablets per day • 40 mg: 1 tablet or packet per day <p><u>Additional exception to the Quantity Limit:</u></p> <ol style="list-style-type: none"> 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 <i>Helicobacter pylori</i>: Additional quantities for doses up to 160 mg per day up to 14 days may be approved. |
| <p>Proventil HFA (albuterol sulfate)</p> | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 inhaler per 30 days <p><u>Additional exception to the Quantity Limit:</u> For individuals with Asthma/Reactive Airway Disease, or Chronic Obstructive Pulmonary Disease (COPD), AND the prescriber attests that the individual needs an</p> |

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| | additional inhaler per 30 days: Approve a one-time override of one inhaler based on the quantities as noted above. |
| Rinvoq (upadacitinib extended-release tablets) Rinvoq LQ (upadacitinib oral solution) | <p>Quantity Limit (Rinvoq extended-release ablets):</p> <ul style="list-style-type: none"> 15 mg: 30 tablets per 30 days 30 mg : 30 tablets per 30 days 45 mg: 56 tablets per 365 days <p>Quantity Limit (Rinvoq LQ oral solution):</p> <ul style="list-style-type: none"> 1 mg/mL (180 mL bottle): 360 mL (2 bottles) per 30 days <p><u>Additional exception to the Quantity Limit:</u></p> <ul style="list-style-type: none"> <u>Rinvoq 15 mg and 30 mg tablets:</u> No overrides recommended <u>Rinvoq LQ oral solution:</u> No overrides recommended <u>Rinvoq 45 mg tablets:</u> <ol style="list-style-type: none"> If the patient is initiating treatment for Crohn's disease or requires additional induction dosing for Crohn's disease, as verified by the absence of claims for Rinvoq in the past 130 days, approve a one-time override for the requested quantity, not to exceed 84 tablets at retail or home delivery. If the patient requires additional induction dosing for Ulcerative Colitis, as verified by the absence of claims for Rinvoq in the past 130 days, approve a one-time override for the requested quantity not to exceed 56 tablets at retail or home delivery. |
| Skyrizi (risankizumab-rzaa) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 75 mg: 1 kit per 84 days = 2 syringes 150 mg: 1 syringe/pen per 84 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose</p> |
| Siliq (brodalumab) | <p>Quantity limit:</p> <ul style="list-style-type: none"> 2 syringes per 28 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose</p> |
| Simponi (golimumab) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 50mg: 1 pen or pre-filled syringe per 28 days 100mg: 1 pen or pre-filled syringe per 28 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Ulcerative Colitis: Quantity limit to FDA recommended dose</p> |
| Stelara (ustekinumab) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 1 pre-filled syringe per 84 days <p><u>Additional exception to the Quantity Limit:</u> 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</p> <p>For induction for Plaque Psoriasis, Psoriatic Arthritis: Quantity limit to FDA recommended dose</p> |
| Symbicort (budesonide / | <p>Quantity Limit:</p> <ul style="list-style-type: none"> 1 inhaler per month |

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| formoterol inhalation aerosol) | <p><u>Additional exception to the Quantity Limit:</u> If the individual has asthma and is using budesonide / formoterol as a reliever therapy, approve up to 2 inhalers per dispensing.</p> |
| Taltz (ixekizumab) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 auto-injector per 28 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Plaque Psoriasis, Psoriatic Arthritis: Quantity limit to FDA recommended dose</p> |
| Tremfya (guselkumab) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 pre-filled syringe per 56 days <p><u>Additional exception to the Quantity Limit:</u> For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose</p> |
| Ventolin HFA (albuterol sulfate) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 inhaler per 30 days <p><u>Additional exception to the Quantity Limit:</u> 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.</p> |
| Vtama (tapinarof cream) | <p>Quantity Limit: 1 tube (60 grams) per 30 days</p> <p><u>Additional exception to the Quantity Limit:</u> 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</p> |
| Xifaxan 550 mg (rifaximin) | <p>Quantity Limit: 550 mg: 42 tabs per 14 days, 126 tabs per 365 days</p> <p><u>Additional exception to the Quantity Limit:</u> For Hepatic Encephalopathy: Quantity limit does not apply</p> |
| Xopenex HFA (levalbuterol) | <p>Quantity Limit:</p> <ul style="list-style-type: none"> • 1 inhaler per 30 days <p><u>Additional exception to the Quantity Limit:</u> 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.</p> |
| Zoryve (roflumilast cream) | <p>Quantity Limit: 1 tube (60 gram tube) per 30 day</p> <p><u>Additional exception to the Quantity Limit</u> 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</p> |

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

1. McEvoy GK, ed. AHFS 2020 Drug Information. Bethesda, MD: American Society of Health-Systems Pharmacists, Inc; 2020.
2. National Research Council. Preventing Medication Errors: Quality Chasm Series. Washington, DC: The National Academies Press, 2007.
3. U.S. Department of Health and Human Services Food and Drug Administration (FDA). FDA Safe Use Initiative. Nov 4, 2009. Accessed 6/14/2020. Available at <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM188961.pdf>
4. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.

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