Drug and Biologic Coverage Policy

Effective Date.....04/01/2026
Coverage Policy Number 1201

Quantity Limitations

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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

POLICY STATEMENT

This Quantity Limitations program has been developed to promote the safe, effective, and economic use of the products listed in the policy. If the Quantity Limitation rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. "One-time" approvals are provided for 30 days in duration.

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 to 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.
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 (120 mL) 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 (240 mL) 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 (480 mL).
Doxepin 5% cream **Prudoxin** (doxepin hydrochloride 5% cream) **Zonalon** (doxepin hydrochloride 5% cream)	**Quantity Limit:** • 90 grams per 30 days **Additional exception to the Quantity Limit:** **1.** If the patient has atopic dermatitis or lichen simplex chronicus and is treating greater than 9% of body surface area, approve a one-time override for the quantity requested not to exceed 180 grams at retail or 450 grams at home delivery. **2.** If the patient has atopic dermatitis or lichen simplex chronicus and requires two 8-day treatment periods per 30 days, approve a one-time override for the quantity requested not to exceed 180 grams at retail or 315 grams at home delivery.
Esomeprazole strontium	**Quantity Limit:** • 49.3 mg: 1 capsule per day **Additional exception to the Quantity Limit:** 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 **Additional exception to the Quantity Limit:** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Ilumya (tildrakizumab-asmn)	**Quantity Limit:** • 1 pre-filled syringe per 84 days **Additional exception to the Quantity Limit:** For induction for Plaque Psoriasis: Quantity limit to FDA recommended dose
Ingrezza (valbenazine capsules) **Ingrezza Sprinkle** (valbenazine capsules)	**Quantity Limit:** • 40 mg, 60 mg and 80 mg: 30 capsules per Rx • Initiation Blister Pack (7 x 40 mg capsules + 21 x 80 mg capsules): 28 capsules per Rx **Additional exception to the Quantity Limit:** Ingrezza 40 mg capsules and Ingrezza Sprinkle 40 mg capsules

	1. If the patient is initiating therapy and is increasing the daily dose from 40 mg to 80 mg daily, approve a one-time override for the requested quantity not to exceed 60 capsules at retail and home delivery.
Krintafel (tafenoquine tablets)	**Quantity Limit:** • 2 tablets per 30 days **<u>Additional exception to the Quantity Limit:</u>** <u>Krintafel 150 mg tablets</u> 1. If the request is for a repeat dose in a patient who has vomited, approve a one-time override of 2 tablets at retail or home delivery.
Livtencity (maribavir)	**Quantity Limit:** • 4 tablets per day **<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 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 **<u>Additional exception to the Quantity Limit:</u>** 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.
Paxlovid (Nirmatrelvir and Ritonavir)	**<u>Quantity Limit</u>** • One course of treatment (1 carton of 5 blister cards) every 120 days **<u>Additional exception to the Quantity Limit:</u>** 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): 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. B) At least 90 days have elapsed since completion of the initial course of Paxlovid for treatment of COVID-19.
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.
Qelbree (viloxazine extended-release capsules)	**Quantity Limit:** • 100 mg: 1 capsule per day • 150 mg: 2 capsules per day • 200 mg: 3 capsules per day **Additional exception to the Quantity Limit:**

	• 100 mg: If the patient is 6 to 11 years of age and is titrating the dose of Qelbree, approve a one-time override for up to 70 capsules • 150 mg: No overrides recommended • 200 mg: No overrides recommended
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 (golimumab)	**Quantity Limit:** • 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
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.
Symbravo (meloxicam and rizatriptan tablets)	**Quantity Limit:** • 9 tablets per 28 days **Additional exception to the Quantity Limit:** If the patient is using the medication to treat intermittent acute migraine headaches (i.e., the request is NOT for continuous/daily use for prevention or prophylaxis), approve a one-time quantity override for an additional 9 tablets at retail or home delivery.
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
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.
Xifaxan 200 mg and 550 mg tablets (rifaximin)	**Quantity Limit:** 200 mg: 9 tablets per 30 days, 27 tablets per 90 days 550 mg: 42 tabs per 30 days, 126 tabs per 90 days **Additional exception to the Quantity Limit:** Xifaxan 200 mg tablets 1. If the patient has chronic antibiotic-dependent pouchitis, approve the requested quantity, not to exceed 300 tablets per dispensing at retail and 900 tablets per dispensing at home delivery. Xifaxan 550 mg tablets 1. 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 days **Additional exception to the Quantity Limit** If a patient needs to treat greater than 8% of their body surface area, approve the requested quantity, not to exceed 180 grams (3 tubes) per 30 days
Zoryve (roflumilast foam)	**Quantity Limit:** • 1 can (60 gram can) per 30 days **Additional exception to the Quantity Limit** If a patient needs to treat greater than 8% of their body surface area, approve the requested quantity, not to exceed 240 grams (4 cans) 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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3. U.S. Department of Health and Human Services Food and Drug Administration (FDA). FDA Safe Use Initiative. Nov 4, 2009. Accessed 6/14/2024. 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/.
5. Barnes EL, Agrawal M, Syal G, et al. AGA clinical practice guideline on the management of pouchitis and inflammatory pouch disorders. Gastroenterology. 2024;166(1):59-85.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	Stelara removed from the policy.	06/01/2025
Selected Revision	Cosentyx removed from the policy.	07/01/2025
Selected Revision	**Added** quantity limits for Xifaxan 200 mg. **Updated** quantity limits for Xifaxan 550 mg.	08/01/2025
Selected Revision	**Removed** Adalimumab quantity limit exception criteria and relocated to a new policy, Inflammatory Conditions – Adalimumab Products Drug Quantity Management Policy – Per Days – (DQM005)	08/15/2025
Selected Revision	**Added** quantity limits for Qelbree **Added** quantity limits for Symbravo. **Added** quantity limits for Zoryve foam.	10/01/2025
Selected Revision	**Added** a policy statement. **Removed** Kineret from the policy.	11/15/2025
Selected Revision	**Removed** Tremfya and relocated to a new policy, Inflammatory Conditions – Tremfya Subcutaneous Drug Quantity Management Policy – Per Days – (DQM012)	12/01/2025

Selected Revision	**Removed** Cimzia and relocated to a new policy, *Inflammatory Conditions – Cimzia Drug Quantity Management Policy – Per Days – (DQM018).* **Removed** Rinvoq/Rinvoq LQ and relocated to new policy, *Inflammatory Conditions – Rinvoq Drug Quantity Management Policy – Per Days – (DQM021)*	02/15/2026
Annual Revision	**Removed** Vtama and relocated to a new policy, *Dermatology – Vtama Drug Quantity Management Policy – Per Days (DQM024).*	04/01/2026

The policy effective date is in force until updated or retired.