DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

POLICY: Immunologicals – Dupixent Drug Quantity Management Policy – Per Days
- Dupixent® (dupilumab subcutaneous injection – Regeneron/sanofi-aventis)

REVIEW DATE: 08/13/2025

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Dupixent, an interleukin-4 receptor alpha antagonist, is indicated for the following uses:[1]

- **Asthma**, as an add-on maintenance treatment in patients ≥ 6 years of age with moderate-to-severe disease with an eosinophilic phenotype or with oral corticosteroid-dependent asthma.
  Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus.
- **Atopic dermatitis**, for the treatment of patients ≥ 6 months of age with moderate-to-severe disease whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- **Bullous pemphigoid,** in adult patients.

- **Chronic obstructive pulmonary disease (COPD),** as an add-on maintenance treatment in adults with inadequately controlled COPD and an eosinophilic phenotype.
  Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm.
- **Chronic rhinosinusitis with nasal polyposis (CRSwNP)** [i.e., nasal polyps], as an add-on maintenance treatment in adults with inadequately controlled disease.
- **Chronic spontaneous urticaria**, in patients ≥ 12 years of age who remain symptomatic despite H_1 antihistamine treatment.
  Limitation of Use: Dupixent is not indicated for the treatment of other forms of urticaria.
- **Eosinophilic esophagitis**, in patients ≥ 1 year of age who weigh ≥ 15 kg.
- **Prurigo nodularis**, in adult patients.

Dosing

Table 1. Dosing and Administration of Dupixent.[1]

Indication	Dosing and Administration
Atopic Dermatitis	Patients ≥ 18 years of age: • 600 mg (two 300 mg SC injections), followed by 300 mg SC Q2W Patients 6 to 17 years of age: • Patients weighing 15 to < 30 kg: 600 mg (two 300 mg SC injections), followed by 300 mg SC Q4W • Patients weighing 30 kg to < 60 kg: 400 mg (two 200 mg SC injections), followed by 200 mg SC Q2W • Patients weighing ≥ 60 kg: 600 mg (two 300 mg SC injections), followed by 300 mg SC Q2W Patients 6 months to 5 years of age: • 5 kg to < 15 kg: 200 mg (one 200 mg SC injection) Q4W • 15 kg to < 30 kg: 300 mg (one 300 mg SC injection) Q4W
Asthma	Adults and Adolescents ≥ 12 years of age: • Initial loading dose of 400 mg (two 200 mg injections), followed by 200 mg SC Q2W; OR • Initial loading dose of 600 mg (two 300 mg injections), followed by 300 mg SC Q2W* Patients 6 to 11 years of age:† • Patients weighing 15 to < 30 kg: 100 mg SC Q2W OR 300 mg SC Q4W • Patients weighing ≥ 30 kg: 200 mg SC Q2W
Bullous Pemphigoid	Patients ≥ 18 years of age: • Initial loading dose of 600 mg (two 300 mg injections), followed by 300 mg SC Q2W
COPD	Patients ≥ 18 years of age: • 300 SC Q2W

Table 1 continued. Dosing and Administration of Dupixent.[1]

Indication	Dosing and Administration
CRSwNP	Patients ≥ 18 years of age: 300 mg SC Q2W
CSU	Patients ≥ 18 years of age: • 600 mg (two 300 mg SC injections), followed by 300 mg SC Q2W Patients 12 to 17 years of age: • Patients weighing 30 kg to < 60 kg: Initial loading dose of 400 mg (two 200 mg injections), followed by 200 mg SC Q2W; OR • Patients weighing ≥ 60 kg: 600 mg (two 300 mg SC injections), followed by 300 mg SC Q2W

EoE	Patients ≥ 1 year of age: • Patients weighing 15 to < 30 kg: 200 mg Q2W • Patients weighing 30 kg to < 40 kg: 300 mg Q2W • Patients weighing ≥ 40 kg: 300 mg SC QW
Prurigo Nodularis	Patients ≥ 18 years of age: • 600 mg (two 300 mg SC injections), followed by 300 mg SC Q2W

SC – Subcutaneous; Q2W – Once every 2 weeks; Q4W – Once every 4 weeks; * The 600 mg loading dose followed by 300 mg once every 2 weeks is the recommended regimen for patients with oral corticosteroid-dependent asthma, patients with co-morbid moderate-to-severe atopic dermatitis, or adults with co-morbid chronic rhinosinusitis with nasal polyposis; † For pediatric patients 6 to 11 years of age with asthma and co-morbid moderate-to-severe atopic dermatitis, follow the recommended dose for atopic dermatitis; CRSwNP – Chronic rhinosinusitis with nasal polyposis; CSU – Chronic spontaneous urticaria; EoE – Eosinophilic esophagitis; QW – Once weekly; COPD – Chronic obstructive pulmonary disease.

Availability

Dupixent is available as 200 mg/1.14 mL and 300 mg/2 mL prefilled pens and prefilled syringes.[1] A 100 mg/0.67 mL prefilled syringe was also previously available, but has been discontinued. Each carton contains either two prefilled pens or prefilled syringes. The prefilled pens are only approved for use in patients ≥ 2 years of age, while the prefilled syringes can be used in patients ≥ 6 months of age.

POLICY STATEMENT

This Drug Quantity Management program has been developed to promote the safe, effective, and economic use of Dupixent. If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals will be provided for 1 year in duration, unless noted below. "One-time" approvals are provided for 30 days in duration.

Drug Quantity Limits

Product	Strength and Form	Retail Maximum Quantity per 28 days	Home Delivery Maximum Quantity per 84 days
Dupixent® (dupilumab subcutaneous injection)	100 mg/0.67 mL syringes	2 syringes (200 mg)	6 syringes (600mg)
	200 mg/1.14 mL pens	400 mg (2 pens)	1,200 mg (6 pens)
	200 mg/1.14 mL syringes	400 mg (2 syringes)	1,200 mg (6 syringes)
	300 mg/2 mL pens	600 mg (2 pens)	1,800 mg (6 pens)
	300 mg/2 mL syringes	600 mg (2 syringes)	1,800 mg (6 syringes)

EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.

CRITERIA

Dupixent 100 mg/0.67 mL syringes

No overrides recommended.

Dupixent 200 mg/1.14 mL pens and syringes

1. If the patient is initiating therapy at induction dosing for asthma, atopic dermatitis, or chronic spontaneous urticaria, as verified by the absence of claims for Dupixent in the past 130 days, approve a one-time override for 800 mg (4 pens or syringes) at retail or 1,600 mg (8 pens or syringes) at home delivery.
Note: The retail quantity of four pens or syringes provides a quantity sufficient for the initial loading dose of 400 mg followed by 200 mg once every 2 weeks thereafter for 28 days. The home delivery quantity of eight pens or syringes provides for the initial loading dose of 400 mg followed by 200 mg once every 2 weeks thereafter for a total of 84 days.

Dupixent 300 mg/2 mL pens and syringes

1. If the patient is initiating therapy at induction dosing for asthma, atopic dermatitis, bullous pemphigoid, chronic spontaneous urticaria, or prurigo nodularis, as verified by the absence of claims for Dupixent in the past 130 days, approve a one-time override for up to 1,200 mg (4 pens or syringes) at retail or 2,400 mg (8 pens or syringes) at home delivery.
Note: The retail quantity of four pens or syringes provides a quantity sufficient for the initial loading dose of 600 mg followed by 300 mg once every 2 weeks thereafter for 28 days. The home delivery quantity of eight pens or syringes provides for the initial loading dose of 600 mg followed by 300 mg once every 2 weeks thereafter for a total of 84 days.

2. If the patient has eosinophilic esophagitis, approve 1,200 mg (4 pens or syringes) per 28 days at retail and 3,600 mg (12 pens or syringes) per 84 days at home delivery.

REFERENCES

1. Dupixent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron/sanofi-aventis; September 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/01/2023
Early Annual Revision	No criteria changes. To help clarify the correct number of syringes for approval, the total milligrams was inserted throughout the Policy.	02/20/2024
Annual Revision	Policy statement was updated to note that "one-time" approvals are provided for 30 days in duration. **Dupixent 100 mg/0.67 mL prefilled syringes:** Override criteria were updated to reflect the override amount in "number of prefilled syringes" instead of "mg".	02/19/2025
Early Annual Revision	**Dupixent 200 mg/1.14 mL pens and syringes:** The one-time override was updated to approve 800 mg (4 pens or syringes) at retail or 1,600 mg (8 pens or syringes) at home delivery if the patient is initiating therapy at induction dosing for asthma, atopic dermatitis, or	08/13/2025

	chronic spontaneous urticaria. Previously, this override provided an approval if the patient was initiating therapy at induction dosing for asthma or atopic dermatitis. **Dupixent 300 mg/2 mL pens and syringes:** The one-time override was updated to approve 1,200 mg (4 pens or syringes) at retail or 2,400mg (8 pens or syringes) at home delivery for a patient initiating therapy at induction dosing for asthma, atopic dermatitis, bullous pemphigoid, chronic spontaneous urticaria, or prurigo nodularis. Previously, this override provided an approval if the patient was initiating therapy at induction dosing for asthma, atopic dermatitis, or prurigo nodularis.	