DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

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

REVIEW DATE: 02/20/2024

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 AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. 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.
- **Chronic rhinosinusitis with nasal polyposis (CRSwNP)** [i.e., nasal polyps], as an add-on maintenance treatment in adults with inadequately controlled disease.
- **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
CRSwNP	Patients ≥ 18 years of age: • 300 mg SC Q2W

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

Indication	Dosing and Administration
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; EoE – Eosinophilic esophagitis; QW – Once weekly.

Availability

Dupixent is available as 200 mg/1.14 mL and 300 mg/2 mL prefilled pens and prefilled syringes.[1] It is also available as 100 mg/0.67 mL prefilled syringes. 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.

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 prefilled syringes	200 mg (2 prefilled syringes)	600 mg (6 prefilled syringes)
	200 mg/1.14 mL prefilled pens	400 mg (2 prefilled pens)	1,200 mg (6 prefilled pens)
	200 mg/1.14 mL prefilled syringes	400 mg (2 prefilled syringes)	1,200 mg (6 prefilled syringes)
	300 mg/2 mL prefilled pens	600 mg (2 prefilled pens)	1,800 mg (6 prefilled pens)
	300 mg/2 mL prefilled syringes	600 mg (2 prefilled syringes)	1,800 mg (6 prefilled syringes)

Immunologicals – Dupixent Drug Quantity Management Policy – Per Days product(s) is(are) covered as medically necessary when the following criteria is(are) met. Any other exception is considered not medically necessary.

CRITERIA

Dupixent 100 mg/0.67 mL prefilled syringes
No overrides recommended.

Dupixent 200 mg/1.14 mL prefilled pens and prefilled syringes

1. If the patient is initiating therapy at induction dosing for asthma or atopic dermatitis, as verified by the absence of claims for Dupixent in the past 130 days, approve a one-time override for 800 mg (4 prefilled pens or prefilled syringes) at retail or 1,600 mg (8 prefilled pens or prefilled syringes) at home delivery.
Note: The retail quantity of four prefilled pens or prefilled 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 prefilled pens or prefilled 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 prefilled pens and prefilled syringes

1. If the patient is initiating therapy at induction dosing for asthma, atopic dermatitis, 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 prefilled pens or prefilled syringes) at retail or 2,400 mg (8 prefilled pens or prefilled syringes) at home delivery.
Note: The retail quantity of four prefilled pens or prefilled 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 prefilled pens or prefilled 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 prefilled pens or prefilled syringes) per 28 days at retail and 3,600 mg (12 prefilled pens or prefilled syringes) per 84 days at home delivery.

REFERENCES

1. Dupixent® subcutaneous injection [prescribing information]. Tarrytown, NY: Regeneron/Sanofi-Aventis; January 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 correct number of syringes for approval, the total milligrams was inserted throughout the Policy.	02/20/2024