

Dupilumab

Adjudication Guideline

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1. Abstract

1.1 For Members

Dupilumab is an injectable prescription medication administered subcutaneously to treat severe and refractory forms of atopic dermatitis. Dupilumab is also used as maintenance treatment for asthma and chronic rhinosinusitis with nasal polyposis in both adults and children, in conjunction with other medications.

1.2 For Medical Professionals

Dupilumab is a human monoclonal antibody administered subcutaneously to inhibit the interleukin-4 receptor subunit α (IL-4R α).

2. Scope

This Adjudication Rule highlights the coverage and payment requirements by Daman as per policy terms and conditions for Dupilumab. It also highlights the medical criteria for coverage.

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

Medical Indications ¹:

Dupilumab is an injectable prescription medicine, interleukin-4 receptor alpha antagonist indicated for the treatment of

1. **Atopic Dermatitis:** For the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.
2. **Asthma:** as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. *Not for the relief of acute bronchospasm or status asthmaticus.*
3. **Chronic Rhinosinusitis with Nasal Polyposis:** as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
4. **Eosinophilic Esophagitis:** for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).
5. **Prurigo Nodularis:** for the treatment of adult patients with prurigo nodularis (PN).

6. **Chronic Obstructive Pulmonary Disease:** Dupilumab is indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
7. **chronic spontaneous urticaria:** Dupilumab is indicated for the treatment of chronic spontaneous urticaria (CSU) in patients aged 12 years and older

DOSAGE AND ADMINISTRATION ¹:

1. Atopic Dermatitis:

- **Dosage in Adults:** Recommended dosage is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.
- **Dosage in Pediatric Patients 6 Months to 5 Years of Age**

Body Weight Initial and Subsequent Dosage	Body Weight Initial and Subsequent Dosage
5 to less than 15 kg 200 mg (one 200 mg injection) every 4 weeks	5 to less than 15 kg 200 mg (one 200 mg injection) every 4 weeks
15 to less than 30 kg 300 mg (one 300 mg injection) every 4 weeks	15 to less than 30 kg 300 mg (one 300 mg injection) every 4 weeks

- **Dosage in Pediatric Patients 6 Years to 17 Years of Age**

Body Weight	Initial Loading Dose	Subsequent Dosage
15 to less than 30 kg	600 mg (two 300 mg injections)	300 mg Q4W
30 to less than 60 kg	400 mg (two 200 mg injections)	200 mg Q2W
60 kg or more	600 mg (two 300 mg injections)	Q2W

*Q2W – every other week; Q4W – every 4 weeks

2. Asthma

- **Dosage in Adult and Pediatric Patients 12 Years and Older**

Initial Loading Dose	Subsequent Dosage
400 mg (two 200 mg injections)	200 mg every 2 weeks (Q2W)
OR	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)
Dosage for patients with oral corticosteroid-dependent asthma or with co-morbid moderate-to-severe atopic dermatitis or adults with comorbid chronic rhinosinusitis with nasal polyposis	
600 mg (two 300 mg injections)	300 mg every 2 weeks (Q2W)

- **Dosage in Pediatric Patients 6 to 11 Years of Age**

Body Weight	Initial Dose and Subsequent Dosage
15 to less than 30 kg	100 mg every other week (Q2W) or 300 mg every four weeks (Q4W)
≥30 kg	200 mg every other week (Q2W)

For pediatric patients 6 to 11 years old with asthma and co-morbid moderate to-severe atopic dermatitis, follow the recommended dosage as per the Table for Dosage in Pediatric Patients 6 Years to 17 Years of Age in atopic dermatitis which includes an initial loading dose

3. **Chronic Rhinosinusitis with Nasal Polyposis:** Recommended dosage for adult patients is 300 mg given every other week (Q2W).
4. **Eosinophilic Esophagitis:** Recommended dosage for adult and pediatric patients 12 years of age and older, weighing at least 40 kg, is 300 mg given every week (QW).
5. **Prurigo Nodularis:** Recommended dosage for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week (Q2W).
6. **Chronic Obstructive Pulmonary Disease:** The recommended dosage of DUPIXENT for adult patients is 300 mg given every other week (Q2W).
7. **Chronic spontaneous urticaria** The recommended dose of Dupixent for adult patients is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week.

Adolescent patients 12 to 17 years of age: •Body Weight of Patient less than 60 kg is an initial dose of 400 mg (two 200 mg injections), followed by 200 mg given every other week administered as subcutaneous injection

• Body Weight of Patient 60 kg or more is an initial dose of 600 mg (two 300 mg injections), followed by 300 mg given every other week administered as subcutaneous injection.

Medical Eligibility Criteria – Dupilumab for Asthma

Dupilumab is indicated as an add-on anti-IL4Ra therapy for patients with severe eosinophilic/Type 2 asthma who remain uncontrolled despite optimized standard treatment.

Eligibility requires that all of the following criteria are met:(A,B,C)

A. The patient must have either:

- A blood eosinophil count ≥ 150 cells/ μ L and ≤ 1500 cells/ μ L while receiving oral corticosteroids within the past 12 months **OR**
- Total serum human immunoglobulin E ≥ 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, performed within the last 12 months

B. The patient has uncontrolled asthma, demonstrated by at least one of the following within the past year:

- Two or more asthma exacerbations require oral or injectable corticosteroids
- One or more asthma exacerbations resulting in hospitalization or emergency medical care visit
- Poor symptom control (frequent symptoms or reliever use, activity limitation due to asthma, or night waking due to asthma)

C. The patient has inadequate asthma control despite current treatment with both of the following at optimized doses:

- High-dose inhaled corticosteroid (ICS)
- Long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated

Medical Eligibility Criteria – Dupilumab for Atopic Dermatitis

Dupilumab, an IL-4/IL-13 receptor-alpha antagonist, is approved for the treatment of moderate to severe atopic dermatitis (AD) in adults and children ≥ 6 months of age.

Patients are eligible for Dupilumab therapy when **all** of the following criteria are met: (A & B)

A. Confirmed Diagnosis of Moderate to Severe Atopic Dermatitis

- DLQI ≥ 10
- BSA $> 10\%$
- SCORAD ≥ 25
- EASI ≥ 7

B. Inadequate Response to Standard Therapy

- Failure to achieve adequate control after at least 8 weeks of:
 - Optimized topical corticosteroid therapy
 - Topical calcineurin inhibitors (TCI)
 - Phototherapy (e.g., NBUVB or UVA1), if feasible and acceptable
- Or documented contraindication or intolerance to these therapies

Evaluation of Treatment Response and continuation criteria

- Re-evaluation of Dupilumab's efficacy should be conducted after a 16-week trial period.
- Treatment success is defined as:
 - DLQI ≤ 5 and/or
 - Improvement in Physician's Global Assessment (PGA) by ≥ 2 points from a baseline of ≥ 3
- Treatment failure is defined as:
 - DLQI ≥ 6 and
 - PGA improvement < 2 points or no improvement
- Continuation of therapy is recommended only if treatment success is achieved.

Red flags:

- In infants and young children, consider short-term therapy with wet or dry bandages/dressings combined with emollients or low-potency topical corticosteroids (TCS) before initiating biologic therapy.
- For children aged 6 months and older and adults with dermatitis not controlled by daily use of potent TCS, dupilumab is recommended as the first-line biologic therapy.
- Continue dupilumab treatment until stable disease control is achieved, then taper dosing frequency appropriately to maintain control.

Missed Dose ¹:

- If a weekly dose is missed, administer the dose as soon as possible, and start a new weekly schedule from the date of the last administered dose.
- If every other week dose is missed, administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, wait until the next dose on the original schedule.
- If every 4-week dose is missed, administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, administer the dose, starting a new schedule based on this date.

Pediatric Uses ¹:

- Atopic Dermatitis: safety and effectiveness has been established in pediatric patients 6 months of age and older with moderate-to-severe atopic dermatitis.
- Asthma: The safety and effectiveness as an add-on maintenance treatment in patients with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma have been established in pediatric patients 6 years of age and older.
- Chronic Rhinosinusitis with Nasal Polyposis: Safety and effectiveness in pediatric patients younger than 18 years of age with have not been established.
- Eosinophilic Esophagitis: The safety and effectiveness have been established in pediatric patients 12 years of age and older, weighing at least 40 kg.

Vaccination Prior to Treatment ¹:

Consider completing all age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment.

Eligible clinical specialties

Eligible clinical specialties
Dermatologist
Allergist and immunologist
Family Medicine
Internal Medicine
Paediatrics
Gastroenterology
Respiratory/Pulmonology

Scoring systems:

➤ For more details on EASI scoring system, review the below link:

- <https://dermnetnz.org/topics/easi-score>
- <http://www.homeforeczema.org/documents/easi-user-guide-dec-2016-v2.pdf>

➤ IGA:

- https://www.eczemacouncil.org/assets/docs/Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf

Validated Investigator Global Assessment scale for Atopic Dermatitis VIGA-AD™

Instructions:

The IGA score is selected using the descriptors below that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

Score	Morphological Description
0 – Clear	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.
1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3 – Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.

3.2 Requirements for Coverage

Failure to submit, upon request or when requesting a clinical history, an indication and the need for testing will result in the rejection of the claim.

3.3 Non-Coverage

- Dupilumab is not covered when the above criteria are not met.
- Coverage as per member SOB

3.4 Payment and Coding Rules

Please apply regulator payment rules and regulations and relevant coding manuals for ICD, CPT, etc.

4. Denial Codes

DOH denial codes with description are elaborated for reference. These are specialized codes directed by DOH, that explains the reason of rejection of the service by DAMAN to the providers

Code	Code Description
MNEC 003	Diagnoses are not covered
MNEC 004	Service is not clinically indicated based on good clinical practice
CODE-010	Activity/diagnosis inconsistent with clinician's specialty
CLN-001	Activity/diagnosis inconsistent with clinician specialty
NCOV-003	Service(s) is (are) not covered
Auth-001	Prior approval is required and was not obtained

5. Appendices

5.1 References

1. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/761055s044lbl.pdf
2. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2022/761055Orig1s040.pdf
3. <https://www.ema.europa.eu/en/medicines/human/EPAR/dupilixent>

5.2 Revision History

Date	Change(s)
19/04/2023	Release of V1.0
23/05/2023	Update: added prurigo nodularis as FDA approved indication
21/11/2024	Update: Added chronic spontaneous urticaria, Chronic Obstructive Pulmonary Disease indication and dose.
28/10/2025	Added eligibility criteria for Dupilumab for Atopic Dermatitis & asthma

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