# Dupilumab

## Adjudication Guideline

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| Daman | Pharmacy Standards & Governance | NA |

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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:** Dupliumab 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.

## 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 an 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 an 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 specialities

| Eligible clinical specialities |
|---|
| 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

- Dupilmuab 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/dupixent*


## 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. |

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