

Dupilumab – Dupixent[®] Drug Use Criteria

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Includes:

Dupixent[®] (Dupilumab)

GUIDELINE FOR USE:

Initial Request: Complete all criteria below for the relevant indication.

Atopic Dermatitis (AD)

Initial Authorization

1. Does the member have a diagnosis of severe atopic dermatitis? (functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on another validated tool) AND one or more of the following:
 - At least 10% body surface area involved, or
 - Hand, foot, face, or mucous membrane involvement
 - a. If yes, go to 2.
 - b. If no, deny as not meeting criteria.

2. Is Dupixent (Dupilumab) prescribed by or in consultation with a dermatologist/allergist/immunologist?
 - a. If yes, go to 3
 - b. If no, deny as not meeting criteria. Please refer member to a specialist (dermatologist/allergist/immunologist) for further evaluation.

3. Has the member failed TWO of the following:
 - combination of topical moderate to high potency topical steroids and a topical non-steroidal agent for at least 4 weeks
 - Oral DMARD (e.g., methotrexate, cyclosporine, mycophenolate mofetil, azathioprine) for at least 12 weeks
 - Phototherapy (2 to 3 sessions per week for 8 to 12 weeks)
 - a. If yes, go to 4
 - b. If no, deny as not meeting criteria.

4. Is the request for every-other-week dosing per FDA labeling?
 - a. If yes, approve for up to 6 months.
 - b. If no, deny as not meeting criteria.

Renewal Criteria (AD)

1. Has the member experienced $\geq 50\%$ reduction in disease severity *or* demonstrated significant functional improvement?
 - a. If yes, approve for up to 12 months.
 - b. If no, deny as not meeting criteria.

Asthma (Eosinophilic Phenotype or Oral Corticosteroid-Dependent)

Initial Authorization

1. Is the request submitted by a pulmonologist or allergist?
 - a. If yes, go to 2.
 - b. If no, deny as not meeting criteria.

2. Does the member have severe asthma uncontrolled despite:
 - High-dose inhaled corticosteroid + LABA
 - Leukotriene modifier
 - Long-acting muscarinic antagonist
 - a. If yes, go to 3.
 - b. If no, deny as not meeting criteria.

3. Is the asthma eosinophilic phenotype or oral corticosteroid-dependent?
 - a. If eosinophilic, go to 4.
 - b. If steroid-dependent, go to 6.
 - c. If neither, deny as not meeting criteria.

4. Has the member had frequent exacerbations requiring urgent care, ED visits, or hospitalization in the past 12 months?
 - a. If yes, go to 5.
 - b. If no, deny as not meeting criteria.

5. Does the member have a blood eosinophil count ≥ 150 cells/ μ L within the past 6 months?
 - a. If yes, approve for 6 months.
 - b. If no, deny as not meeting criteria.

6. Does the member require ongoing oral corticosteroids to maintain asthma control?
 - a. If yes, approve for 6 months.
 - b. If no, deny as not meeting criteria.

Renewal Criteria (Asthma)

1. Has the member had reduced exacerbations or decreased oral corticosteroid use with sustained clinical improvement?
 - a. If yes, approve for 12 months.
 - b. If no, deny as not meeting criteria.

Bullous Pemphigoid

Initial Authorization

1. Is the request from a dermatologist?
 - a. If yes, continue to #2.
 - b. If no, deny as not meeting criteria.

2. Does the member have a histopathologic diagnosis of bullous pemphigoid, such as biopsy confirmed disease?
 - a. If yes, continue to #3.
 - b. If no, deny as not meeting criteria.

3. Has the member failed oral corticosteroids (steroids have failed to improve pruritus, improve current lesions, and prevent new lesions from forming)?
 - a. If yes, Continue to #4.
 - b. If no, deny as not meeting criteria.

4. Has the member failed a 3-month trial of one of the following drugs or have a contraindication to all of the following?
 - Azathioprine
 - Methotrexate
 - Mycophenolate

***If one of these drugs is not tolerated, a different must be tried before considering oral therapy failed.

 - a. If yes, continue to #5.
 - b. If no, deny as not meeting criteria.

5. Has the member been prescribed oral corticosteroid therapy along with Dupixent?
 - a. If yes, approve for up to 6 months
 - b. If no, deny as not meeting criteria.

Renewal Criteria (Bullous Pemphigoid)

1. Has the member demonstrated a significant improvement compared to baseline, such as significant improvement in pruritus, healing of lesions, or ability to taper off of systemic corticosteroids?
 - a. If yes, continue to #2.
 - b. If no, deny as not meeting criteria.

2. Has the provider determined that tapering off of therapy is not appropriate, and continued use of Dupixent is medically necessary?
 - a. If yes, approve for 12 months.
 - b. If no, deny as not meeting criteria.

Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)

Initial Authorization

1. Is the request from an ENT or allergist?
 - a. If yes, go to 2.
 - b. If no, deny as not meeting criteria.

2. Does the member have recurrent nasal polyps after multiple prior sinus surgeries?
 - a. If yes, go to 3.
 - b. If no, deny as not meeting criteria.

3. Has the member failed:
 - ≥ 2 intranasal corticosteroids, and
 - Sinuva (if appropriate)?
 - a. If yes, go to 4.
 - b. If no, deny as not meeting criteria.

4. Is the member adherent to intranasal corticosteroid therapy?
 - a. If yes, go to 5.
 - b. If no, deny as not meeting criteria.

5. Is the member at risk for another sinus surgery, and is surgery not medically appropriate?
 - a. If yes, consult medical director.
 - b. If no, deny as not meeting criteria.

Renewal Criteria (CRSwNP)

1. Has the member had clinically significant improvement and reduced risk of surgery?
 - a. If yes, approve for 6 months.
 - b. If no, deny as not meeting criteria.

Chronic Spontaneous Urticaria

Initial Authorization

1. Is the member an EPSDT or YSHCN beneficiary?
 - a. If yes, continue to #2.
 - b. If no, deny as not meeting criteria. Chronic spontaneous urticaria is below the line of coverage.
2. Is the member at least 12 years old?
 - a. If yes, continue to #3.
 - b. If no, deny as not meeting criteria.
3. Is the drug prescribed by or in consultation with an allergist/immunologist?
 - a. If yes, continue to #4.
 - b. If no, deny as not meeting criteria.
4. Does the member have a documented diagnosis of chronic spontaneous urticaria with the presence of hives and/or angioedema for > 6 weeks?
 - a. If yes, continue to #5.
 - b. If no, deny as not meeting criteria.

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5. Does the member have severe disease necessitating medical treatment including:
 - 50 wheals (hives) or large areas of wheals that blend into each other. AND
 - Itching impacts the member's ability to sleep at night or participate in daily activities (such as participating in school)?
 - a. If yes, continue to #6.
 - b. If no, deny as not meeting criteria.

 6. Has the member failed all of the following treatments?
 - At least two second generation antihistamines (like loratadine and cetirizine)
 - An antihistamine at a higher-than-normal dose (such as cetirizine 20 mg daily)
 - Montelukast
 - Either hydroxyzine or an H2 antagonist (like famotidine or cimetidine)
 - Xolair (with pre-approval)?
 - a. If yes, approve for 6 months
 - b. If no, deny as not meeting criteria.

Renewal Criteria (Chronic Spontaneous Urticaria)

1. Has the member had significant improvement in the condition with at least one of the following?
 - Decrease in wheals (hives) and/or angioedema.
 - Improvement in sleep and/or ability to participate in daily activities.
 - a. If yes, continue to 2.
 - b. If no, deny as not meeting criteria.

2. Has the provider documented that continued treatment is medically necessary and it is not appropriate to taper and stop therapy at this time?
 - a. If yes, approve for up to 12 months.
 - b. If no, deny as not meeting criteria

COPD

Initial Authorization

1. Is there a diagnosis of COPD with chronic bronchitis?
 - a. If yes, continue to #3.
 - b. If no, deny as not meeting criteria.

2. Are there labs documenting a blood eosinophil count (BEC) > 150 cells/ μ L within the past 3 months?
 - a. If yes, continue to #4.
 - b. If no, deny as not meeting criteria.

3. Is there a history of ≥ 2 moderate or ≥ 1 severe COPD exacerbations within the last year despite the adherence to inhaled LABA + LAMA + ICS triple therapy
 - a. If yes, approve for 6 months.
 - b. If no, deny as not meeting criteria

Renewal Criteria (COPD)

1. Has there been clinical improvement in symptoms of COPD and/or a reduction in frequency or severity of exacerbations?
 - a. If yes, approve for up to 12 months
 - b. If no, deny as not meeting criteria.

Eosinophilic Esophagitis (EoE)

Initial Authorization

1. Is the request from a gastroenterologist, surgeon who has performed a biopsy, or an allergist?
 - a. If yes, go to 2.
 - b. If no, deny as not meeting criteria.

2. Is Dupixent indicated for the member's age and weight per FDA labeling?
 - a. If yes, go to 3.
 - b. If no, deny as not meeting criteria.

3. Does the member have biopsy-confirmed eosinophilic esophagitis?
 - a. If yes, go to 4.
 - b. If no, deny as not meeting criteria.

4. Has the member failed ≥ 12 weeks of:
 - High-dose PPI therapy
 - Swallowed topical corticosteroids
 - a. If yes, go to 5.
 - b. If no, deny as not meeting criteria.

5. Has the member failed dietary modification therapy?
 - a. If yes, approve for 6 months.
 - b. If no, deny as not meeting criteria.

Renewal Criteria (EoE)

1. Has the member had clinically significant improvement in symptoms?
 - a. If yes, approve for 12 months.
 - b. If no, deny as not meeting criteria.

Prurigo Nodularis

Initial Authorization

1. Is the member under age 21?
 - a. If yes, go to 2.
 - b. If no, go to 3.

2. Does the member meet all of the following:
 - Has chronic, moderate to severe prurigo nodularis (10% BSA, or hand, foot, face or mucous membrane involvement) with functional impairment; AND
 - Failure of a combination of steroid and non-steroid topical medications.
 - a. If yes, go to 4.
 - b. If no, forward to medical director for review for medical necessity and appropriateness

3. Does the member meet all of the following:
 - Has chronic, moderate to severe prurigo nodularis (10% BSA, or hand, foot, face or mucous membrane involvement) with functional impairment; AND
 - Failure of TWO of the following:
 - combination of topical moderate to high potency topical steroids and a topical non-steroidal agent for at least 4 weeks
 - Oral DMARD (e.g., methotrexate, cyclosporine, mycophenolate mofetil, azathioprine) for at least 12 weeks
 - Phototherapy (2 to 3 sessions per week for 8 to 12 weeks)
 - a. If yes, approve for up to 6 months.
 - b. If no, deny as not meeting criteria.

Renewal Criteria (Prurigo Nodularis)

1. Has the member had a significant response in therapy, such as reduction in the number of nodules, significant decrease in pruritus, and/or functional improvement?
 - a. If yes, approve for up to 12 months
 - b. If no, deny as not meeting criteria.

Rationale: Dupixent® (dupilumab) is a targeted biologic therapy indicated for select chronic inflammatory conditions driven by type 2 inflammation. Due to its high cost and long-term treatment considerations, use should be reserved for members with moderate-to-severe disease who have failed appropriate conventional therapies and demonstrate clinically significant disease burden or functional impairment. These criteria are intended to support evidence-based prescribing, ensure specialist involvement when appropriate, promote stepwise therapy consistent with clinical guidelines, and require documentation of meaningful clinical improvement for continued therapy.

FDA Indications: Dupixent® (dupilumab) is approved for the treatment of moderate-to-severe atopic dermatitis, asthma with an eosinophilic phenotype or oral corticosteroid dependence, chronic rhinosinusitis with nasal polyps (CRSwNP), eosinophilic esophagitis (EoE), prurigo nodularis, chronic obstructive pulmonary disease (COPD) with an eosinophilic phenotype, and chronic spontaneous urticaria (CSU) in appropriately selected patients.

References:

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12. American Gastroenterological Association Clinical Practice Update on Management of Eosinophilic Esophagitis. *Gastroenterology*. Updated 2024.
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14. Oregon Health Authority Prioritized List of Health Services and applicable Oregon Administrative Rules (OARs). Current version.