**Overview**

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by binding to the IL-4Rα subunit. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of proinflammatory cytokines, chemokines, nitric oxide and IgE.

**Coverage Guidelines**

Authorization may be granted for members who are currently receiving Dupixent for an approved indication, excluding when the product is obtained as samples or via manufacturer’s patient assistance program.

OR

Approval of Dupixent® will be granted if the member meets the following diagnosis specific criteria and documentation has been submitted:

**Moderate-severe atopic dermatitis:**

1. Member has a diagnosis of moderate-severe atopic dermatitis
2. Member is at least 12 years of age
3. Prescriber is an allergist/immunologist or dermatologist, or provides consultations notes from an allergist/immunologist or dermatologist.
4. Prescriber has provided documentation of ONE of the following:
   a. Inadequate response or adverse reaction to ONE super potent or potent topical corticosteroid †
   b. Contraindication to ALL super potent or potent topical corticosteroids ‡
5. Member has had an inadequate response, adverse reaction or contraindication to topical tacrolimus

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### Specialty Medications

<table>
<thead>
<tr>
<th>Plan</th>
<th>Program Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>MassHealth</td>
<td>☑ Prior Authorization</td>
</tr>
<tr>
<td>Commercial/Exchange</td>
<td>□ Quantity Limit</td>
</tr>
<tr>
<td>Pharmacy Benefit</td>
<td>□ Quantity Limit</td>
</tr>
<tr>
<td>Medical Benefit (NLX)</td>
<td>□ Quantity Limit</td>
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<tr>
<td></td>
<td>✒ Prior Authorization</td>
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<td></td>
<td>□ Quantity Limit</td>
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<td></td>
<td>□ Step Therapy</td>
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</tbody>
</table>

**Specialty Limitations**

This medication has been designated specialty and must be filled at a contracted specialty pharmacy.

**Contact Information**

**Specialty Medications**

<table>
<thead>
<tr>
<th>Plan</th>
<th>Phone</th>
<th>Fax</th>
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</thead>
<tbody>
<tr>
<td>All Plans</td>
<td>866-814-5506</td>
<td>866-249-6155</td>
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**Non-Specialty Medications**

<table>
<thead>
<tr>
<th>Plan</th>
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<tbody>
<tr>
<td>MassHealth</td>
<td>877-433-7643</td>
<td>866-255-7569</td>
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<tr>
<td>Commercial</td>
<td>800-294-5979</td>
<td>888-836-0730</td>
</tr>
<tr>
<td>Exchange</td>
<td>855-582-2022</td>
<td>855-245-2134</td>
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**Medical Specialty Medications (NLX)**

<table>
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<th>Plan</th>
<th>Phone</th>
<th>Fax</th>
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</thead>
<tbody>
<tr>
<td>All Plans</td>
<td>844-345-2803</td>
<td>844-851-0882</td>
</tr>
</tbody>
</table>

**Exceptions**

N/A
6. Prescriber has provided documentation of ONE of the following:
   • Inadequate response or adverse reaction to ONE systemic immunosuppressive therapy* (e.g. azathioprine, cyclosporine, methotrexate, mycophenolate mofetil, mycophenolic acid)
   • Contraindication to ALL systemic immunosuppressive therapy
7. Dosing is appropriate (see Appendix A)

Add-on maintenance treatment of moderate to severe asthma with an eosinophilic phenotype:
1. Member is at least 12 years of age
2. Prescriber is an asthma specialist (i.e. allergist, immunologist, pulmonologist)
3. Member is symptomatic despite receiving one of the following:
   a. combination inhaler containing an inhaled corticosteroid and a long-acting β-agonist
   b. combination of an inhaled corticosteroid and a long-acting β-agonist inhaler as a separate inhaler
   c. member requires chronic oral corticosteroids
4. Evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO
5. Dosing is appropriate (see Appendix A)

Oral corticosteroid dependent asthma:
1. Member is at least 12 years of age
2. Member requires chronic oral steroids for treatment of asthma
3. Dosing is appropriate (see Appendix A)

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP):
1. Member at least 18 years of age
2. Prescriber is a specialist (i.e., allergist, immunologist, pulmonologist)
3. Member is symptomatic despite adjunct therapy with ALL the following:
   a. oral corticosteroid
   b. intranasal corticosteroid
   c. leukotriene antagonist
4. Dosing is appropriate (see Appendix A)

*If member has tried systemic immunosuppressive therapy and trial with a super potent or potent topical corticosteroid has not been documented, the trial may be bypassed
† If member has tried lower potency corticosteroid, prescriber must provide clinical rationale for not utilizing super potent/potent corticosteroid
‡ Trials with corticosteroids may be bypassed if the request clearly states that the treatment area is a sensitive area (facial/groin)

Continuation of Therapy
Reauthorization may be approved when documentation is submitted that satisfies the following diagnosis specific requirements:
1. Atopic Dermatitis or Chronic Rhinosinusitis with Nasal Polyposis – A positive response to therapy.
2. Asthma – A positive response to therapy as evidenced by a decrease in oral steroid requirement and a decrease in asthma exacerbations.

Limitations
1. Initial approvals for all indications will be granted for 6 months
2. Reauthorizations will be granted based on diagnosis:
   a. Atopic Dermatitis – 6 months
   b. Asthma or Chronic Rhinosinusitis with Nasal – 12 months
3. The following quantity limits apply:

<table>
<thead>
<tr>
<th>Dupixent 200mg/1.14mL</th>
<th>400 mg (2.28 mL) per 28 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dupixent 300mg/1mL</td>
<td>600 mg (2mL) per 28 days</td>
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</table>

### Appendix A:

<table>
<thead>
<tr>
<th>Dupixent® (dupilumab)</th>
<th>Atopic dermatitis (moderate-severe): 600 mg SQ followed by 300 mg every other week</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Moderate to severe eosinophilic asthma: 400mg or 600mg followed by 200mg or 300mg every other week</td>
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<tr>
<td></td>
<td>Oral corticosteroid dependent asthma: 600mg followed by 300mg every other week</td>
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<tr>
<td></td>
<td>Chronic rhinosinusitis with nasal polyposis (CRSwNP): 300mg every other week</td>
</tr>
</tbody>
</table>

### References


### Review History
06/06/2017: Reviewed P&T
10/01/2017: Implemented
03/01/2018: Reviewed and Revised (Adopted MH RS)
11/26/2018: Reviewed and Revised
01/22/2019: Added chronic rhinosinusitis with nasal polyposis
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