**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**

Approval 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 **AND**
2. Member is at least 18 years of age **AND**
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 superpotent or potent topical corticosteroid †
   b. Contraindication to ALL superpotent or potent topical corticosteroids ‡

**AND**

5. Member has had an inadequate response, adverse reaction or contraindication to topical tacrolimus **AND**
6. Prescriber has provided documentation of ONE of the following:
   a. 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 **AND**
2. Prescriber is an asthma specialist (i.e. allergist, immunologist, pulmonologist) **AND**
3. Member is symptomatic despite receiving one of the following:
   a. combination inhaler containing an inhaled corticosteroid **and** a long-acting β-agonist; **or**
   b. combination of an inhaled corticosteroid **and** a long-acting β-agonist inhaler as a separate inhaler; **or**
4. Member requires chronic oral corticosteroids **AND**
5. Evidence of an eosinophilic phenotype (i.e., peripheral blood eosinophil count ≥ 150 cells/μL, elevated sputum eosinophils or FeNO **AND**
6. Dosing is appropriate (see Appendix)

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

*If member has tried systemic immunosuppressive therapy and trial with a superpotent 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 superpotent/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**
1. Reauthorizations for Atopic Dermatitis will be approved when documentation is submitted indicating a positive response to therapy.
2. Reauthorizations for Asthma will be approved when documentation is submitted indicating a positive response to therapy as evidenced by a decrease in oral steroid requirement and a decrease in asthma exacerbations.

**Limitations**
1. Initial approvals will be granted for 6 months
2. Reauthorizations will be granted as listed below based on diagnosis
   a. Atopic Dermatitis – 6 months
   b. Asthma – 12 months

**Appendix**

<table>
<thead>
<tr>
<th>Dupixent® (dupilumab)</th>
<th><strong>Atopic dermatitis (moderate-severe):</strong> 600 mg SQ followed by 300 mg every other week</th>
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<tr>
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<td><strong>Moderate to severe eosinophilic asthma:</strong> 400mg or 600mg followed by 200mg or 300mg every other week.</td>
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<td><strong>Oral corticosteroid dependent asthma:</strong> 600mg followed by 300mg every other week</td>
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References
N/A

Review History
06/2017: Reviewed P&T
10/01/2017: Implemented
03/01/2018: Reviewed and Revised (Adopted MH RS)
11/26/2018: Reviewed and Revised

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