## Drug Therapy Guidelines

### Dupixent (dupilumab)

<table>
<thead>
<tr>
<th>Medical Benefit</th>
<th>Effective: 7/19/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy- Formulary 1</td>
<td>X</td>
</tr>
<tr>
<td>Pharmacy- Formulary 2</td>
<td>X</td>
</tr>
<tr>
<td>Pharmacy- Formulary 3/Exclusive</td>
<td>X</td>
</tr>
<tr>
<td>Pharmacy- Formulary 4/AON</td>
<td>X</td>
</tr>
</tbody>
</table>

### I. Medication Description

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by binding specifically to the IL-4R alpha subunit shared by the IL-4 and IL-13 receptor complexes. By blocking IL-4R alpha, dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory response, including the release of proinflammatory cytokines, chemokines, and IgE, which plays a role in the development of atopic dermatitis. Consistent with receptor blockade, serum levels of IL-4 and IL-13 are increased following dupilumab treatment.

### II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

### III. Policy

Coverage of Dupixent is available when the following criteria have been met:

- Patient is at least 18 years of age **AND**
- The medication is prescribed by an allergist, immunologist, or dermatologist **AND**
- Patient has been diagnosed with moderate-to-severe atopic dermatitis **AND**
- Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) according to the prescribing physician **AND**
- In the past 6 months, the patient has tried at least one of the following systemic agents: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil **AND**
- Patient has used at least one medium-, medium-high, high-, and/or super-high-potency prescription topical corticosteroid (or use is shown to be contraindicated) **AND**
- In the past 6 months, the patient has tried a topical calcineurin inhibitor

### IV. Quantity Limitations

- Coverage is available for a loading dose of 600mg (two syringes) followed by 300mg (one syringe) every 2 weeks thereafter.
- Coverage of loading dose must be specifically requested and approved for the required quantity to be covered.
V. Coverage Duration

Coverage is available for 12 months and may be renewed.

VI. Coverage Renewal Criteria

Coverage can be renewed based upon the following criteria:
• Stabilization of disease or in absence of disease progression AND
• Absence of unacceptable toxicity from the drug

VII. Billing/Coding Information

• Available in cartons containing 2 prefilled syringes.
• Each syringe delivers 300mg of Dupixent in a 2ml solution.

VIII. Summary of Policy Changes

7/19/17: new policy

IX. References


The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.