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:

- Member is at least 18 years of age AND
- The medication is prescribed by an allergist, immunologist, or dermatologist AND
- Member has been diagnosed with moderate-to-severe atopic dermatitis AND
- Member has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) according to the prescribing physician AND
- Member has tried at least one of the following systemic medications: oral corticosteroid, intramuscular corticosteroid, oral cyclosporine, oral azathioprine, oral methotrexate, or oral mycophenolate mofetil AND
- Member 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
- Member has tried a topical calcineurin inhibitor (unless use is contraindicated).

IV. Quantity Limitations

- Coverage is available as follows:
  - Up to 8 ml (4 syringes) are covered in the first month to accommodate induction dosing
  - Up to 4 ml (2 syringes) are covered in subsequent months to accommodate maintenance dosing
• 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
- 10/11/17: removed time frame for trials of systemic medications and topical calcineurin inhibitor; quantity limitations updated
- 11/1/18: no policy changes

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.