

Clinical Oversight Review Board (CORB) Criteria for Prescribing / Criteria-Based Consultation (CBC) Criteria for Coverage

dupilumab (Dupixent)

Non-formulary **dupilumab (Dupixent)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Atopic Dermatitis

- Prescriber is a Dermatologist or Allergist **-AND-**
- Patient is at least 12 years of age **-AND-**
- Diagnosis of moderate to severe atopic dermatitis (the most common type of eczema that makes your skin red and itchy) **-AND-**
- History of failure, contraindication, or intolerance to at least one of the following topical therapies:
 - i. Medium to very-high potency topical corticosteroid **-OR-**
 - ii. Topical calcineurin inhibitor (e.g., pimecrolimus, tacrolimus)

-AND-

- History of failure, contraindication, or intolerance to narrow-band short wave ultraviolet B (NB-UVB) light **-AND-**
- History of inadequate response (after at least 1 month of treatment), intolerance, or contraindication to at least 2 of the following systemic therapies:
Azathioprine, cyclosporine, methotrexate, mycophenolate

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Asthma

- Prescriber is an allergist or pulmonologist **-AND-**
- Patient is at least 12 years of age **-AND-**
- Diagnosis of moderate to severe asthma and either of the following:
 - i. Patient uses systemic corticosteroids daily to control asthma; **-OR-**
 - ii. Patient has an eosinophilic phenotype related to asthma defined as:
A peripheral blood eosinophil count of at least 150 cells/microliter in the past 6 weeks OR at least 300 cells/microliter in the past 12 months

-AND-

- Patient has uncontrolled asthma defined as any of the following:
 - i. Two or more exacerbations in the past 12 months requiring systemic corticosteroids for more than 3 days; **-OR-**
 - ii. Serious asthma exacerbations leading to at least one hospitalization in the past 12 months; **-OR-**
 - iii. Dependence on daily oral corticosteroids for asthma control

-AND-

- Patient has uncontrolled asthma despite adherence to (at least 75% over the past 3 months) a regimen containing high dose inhaled corticosteroid (ICS), **AND** one additional asthma controller medication: a long-acting beta₂ agonist (LABA); **OR** a leukotriene receptor antagonist (LRTI [e.g., montelukast, zafirlukast]); **OR** a long-acting muscarinic antagonist (e.g., tiotropium)

-AND-

- Dupilumab is used in combination with a high dose inhaled corticosteroid (ICS) **AND** one additional asthma controller medication: a long-acting beta₂ agonist (LABA); **OR** a leukotriene receptor antagonist (LRTI [e.g., montelukast, zafirlukast]); **OR** a long-acting muscarinic antagonist (e.g., tiotropium)

-AND-

- Dupilumab will NOT be used in combination with any of the following:
 - i. Anti-interleukin-5 therapy (e.g. Nucala [mepolizumab], Cinqair [reslizumab], Fasentra [benralizumab]); **-OR-**
 - ii. Anti-IgE therapy (e.g. Xolair [omalizumab])

-OR-

- Patient is currently on dupilumab therapy **AND** it is being used in combination with an inhaled corticosteroid **AND** asthma controller medication (e.g., LABA, LRTI, or LAMA) **-OR-** oral steroids for asthma control.