

<b>PA Description</b>	<b>Dupilumab (Dupixent)</b>
<b>Managed by</b>	Managed Care Organizations (MCOs) contracted by the Puerto Rico Health Insurance Administration (known in Spanish as <i>Administración de Seguros de Salud</i> or ASES) to provide pharmacy services to the insured of the Government Health Plan.
<b>Covered Uses</b>	<p>(a) Treatment of patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. (ICD-10-CM L20.81, ICD-10-CM L20.9)</p> <p>(b) As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. (ICD-10-CM J45.5, ICD-10-CM J82)</p> <p>(c) As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP). (ICD-10-CM J32.9, ICD-10-CM J33.9)</p> <p>(d) Treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE). (ICD-10-CM K20.0)</p>
<b>Exclusion Criteria</b>	(a) None
<b>Required Medical Information</b>	<p>For Atopic Dermatitis: For first prescription only;</p> <p>(a) For moderate atopic dermatitis: Physician documents that:</p> <ul style="list-style-type: none"> <li>(i) Patient has previous use of topical corticosteroids and topical calcineurin inhibitors, and crisaborole, OR</li> <li>(ii) Contraindicated use of topical corticosteroids and topical calcineurin inhibitors and crisaborole.</li> </ul> <p>(b) For severe atopic dermatitis: Physician documents that:</p> <ul style="list-style-type: none"> <li>(i) Patient has previous use of topical corticosteroids and topical calcineurin inhibitors. OR</li> <li>(ii) Contraindicated use of topical corticosteroids and topical calcineurin inhibitors.</li> </ul> <p>For Asthma: For the first prescription: (a) Physician must document all of the following:</p>

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	<p>(i) Classification of asthma as uncontrolled or inadequately controlled as defined by at least one of the following</p> <ol style="list-style-type: none"> <li>1. Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)</li> <li>2. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months</li> <li>3. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)</li> <li>4. Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])</li> <li>5. Patient is currently dependent on oral corticosteroids for the treatment of asthma.</li> </ol> <p style="text-align: center;">-AND-</p> <p>(ii) Dupixent will be used in combination with one of the following:</p> <ol style="list-style-type: none"> <li>1. One high-dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA)</li> </ol> <p style="text-align: center;">-OR-</p> <ol style="list-style-type: none"> <li>2. Combination therapy including both of the following: <ol style="list-style-type: none"> <li>a. One high-dose (appropriately adjusted for age) ICS product</li> </ol> <p style="text-align: center;">-AND-</p> <ol style="list-style-type: none"> <li>b. One additional asthma controller medication</li> </ol> <p style="text-align: center;">-AND-</p> </li> </ol> <p>(iii) One of the following:</p> <ol style="list-style-type: none"> <li>1. Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level <math>\geq</math> 150 cells/<math>\mu</math>L within the past 6 weeks.</li> </ol> <p style="text-align: center;">-OR-</p> <ol style="list-style-type: none"> <li>2. Patient is currently dependent on oral corticosteroids for the treatment of asthma.</li> </ol> <p>For Renewal:</p> <p>(a) Documentation of positive clinical response to Dupixent therapy as demonstrated by at least one of the following:</p>

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	<p>(i) Reduction in the frequency of exacerbations  (ii) Decreased utilization of rescue medications  (iii) Increase in percent predicted FEV1 from pretreatment baseline  (iv) Reduction in severity or frequency of asthma-related symptoms (e.g. wheezing, shortness of breath, coughing, etc.)  (v) Reduction in oral corticosteroid requirements</p> <p style="text-align: center;">-AND-</p> <p>(i) (b) Dupixent is being used in combination with an ICS-containing controller medication.</p> <p>For chronic rhinosinusitis with nasal polyposis:  (a) For the first prescription only: Documentation evidencing that chronic rhinosinusitis remains uncontrolled despite recommended doses of oral (e.g. prednisone) or intranasal glucocorticoids (e.g. fluticasone propionate, mometasone furoate or beclomethasone).  (b) Document use in combination with other systemic glucocorticoids as maintenance treatment.</p> <p>For Eosinophilic Esophagitis:  (a) Documented diagnosis of EoE by endoscopic biopsy  (b) For the first prescription only: Documentation evidencing 2 or more episodes of dysphagia per week.</p>
<b>Age Restriction</b>	<p>(a) For atopic dermatitis: Patients aged 6 months of age or older.  (b) For asthma: Patients aged 6 years of age or older.  (c) For Chronic rhinosinusitis with nasal polyposis: 18 years of age or older.  (d) For Eosinophilic Esophagitis: Patients aged 12 years of age or older weighing at least 40 kg</p>
<b>Prescriber Restriction</b>	<p>(a) For Atopic Dermatitis: Allergist/Immunologist, Dermatologist  (b) For Asthma and Chronic rhinosinusitis with nasal polyposis: Pulmonologist / Pneumologist, Allergist/Immunologist, ENT Physician  (c) For eosinophilic esophagitis: Allergist/Immunologist or Gastroenterologist</p>
<b>Coverage Duration</b>	<p>(a) For Atopic Dermatitis, Asthma, Chronic rhinosinusitis with nasal polyposis and Eosinophilic Esophagitis: Six (6) months  (ii) Renewal: Twelve (12) months</p>
<b>Other Criteria</b>	<p>(a) Refer to the prescribing information for dosage and administration.</p>