

PA Criteria	Criteria Details		
<b>Description</b>	EXDENSUR is an interleukin-5 (IL-5) antagonist, a monoclonal antibody (humanized immunoglobulin G [IgG]1 kappa).		
<b>Covered Uses (FDA approved indication)</b>	EXDENSUR is indicated for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older.		
<b>Dosing and Administration</b>	<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dosage</b>
	Severe Asthma	100 mg via subQ injection Q6 months into upper arm, thigh or abdomen.  <b>EXDENSUR must be administered by a healthcare provider.</b>  <b>DO NOT use for relief of acute bronchospasm or status asthmaticus.</b>	100 mg
<b>Billing and Coding Information</b>	<b>10-digit NDC</b>		<b>11-digit NDC</b>
	0173-0927-42		00173-0927-42
	<b>HCPCS Code</b>		<b>Description</b>
	C9399		Unclassified drugs or biologicals
	J3590		Unclassified biologics
<b>CPT Procedural Codes</b>		<b>Description</b>	
96372		Therapeutic, prophylactic or diagnostic injection; subcutaneous or intramuscular	
<b>Product Availability</b>	Single-dose Prefilled syringe with 29G ½ inch needle – 100 mg/mL		
<b>Contraindications</b>	None.		
<b>Recommended Medical Monitoring</b>	<p>EXDENSUR has been associated with:</p> <ul style="list-style-type: none"> <li>Hypersensitivity reactions, including anaphylaxis</li> </ul> <p><b>Acute Asthma Symptoms or Deteriorating Disease:</b> EXDENSUR should NOT be used to treat acute asthma symptoms or acute exacerbations. Do NOT use to treat acute bronchospasm or status asthmaticus.</p> <p><b>Risk Associated with Abrupt Reduction of Corticosteroid Dosage:</b> Reduction in corticosteroid dose may be associated with systemic withdrawal symptoms and/or unmask conditions previously suppressed by systemic corticosteroid therapy. Do not abruptly discontinue systemic or inhaled corticosteroids upon initiation of EXDENSUR therapy.</p> <p><b>Parasitic (Helminth) Infection:</b> Eosinophils may be involved in the immunological response to some helminth infections. Patients with pre-existing helminth infections were excluded from participation in clinical trials. It is unknown if EXDENSUR will influence a patient’s response against parasitic infections. Patients with pre-existing helminth infections should be treated for their infection prior to initiation of EXDENSUR therapy.</p>		

<b>Approval Criteria</b>	<ul style="list-style-type: none"> <li>a. Physician administered; in-office or HOPD           <ul style="list-style-type: none"> <li>i. Cannot be self-administered</li> </ul> </li> <li>b. Severe Asthma (<b>must meet all</b>):           <ul style="list-style-type: none"> <li>i. Diagnosis of severe asthma characterized by an eosinophilic phenotype:               <ul style="list-style-type: none"> <li>1. Defined as:                   <ul style="list-style-type: none"> <li>a. Blood eosinophil count <math>\geq</math> 150 cells/mcL at start of therapy – <b>OR</b> –</li> <li>b. Blood eosinophil count <math>\geq</math> 300 cells/mcL documented up to one year prior</li> </ul> </li> <li>ii. Prescribed by or in consultation with a pulmonologist or allergist</li> <li>iii. Age <math>\geq</math> 12 years old</li> <li>iv. Two or more asthma exacerbations per year requiring treatment with systemic corticosteroids while on:                   <ul style="list-style-type: none"> <li>1. Medium-to-high-dose inhaled corticosteroid – <b>AND</b> –</li> <li>2. At least one additional asthma controller with or without maintenance oral corticosteroids</li> </ul> </li> <li>v. Reduced lung function at baseline prior to start of therapy                   <ul style="list-style-type: none"> <li>1. Must meet one of the following:                       <ul style="list-style-type: none"> <li>a. FEV1 &lt; 80% predicted normal in adults – OR –</li> <li>b. FEV1 &lt; 90% in pediatric patients <math>\geq</math> 12 yrs old – OR --</li> <li>c. FEV1 to forced vital capacity ratio &lt; 0.8 in pediatric patients <math>\geq</math> 12 yrs old</li> </ul> </li> </ul> </li> </ul> </li> <li>iv. Dose does not exceed 100 mg subcutaneously Q6 months</li> </ul> </li> </ul>
<b>Age Restriction</b>	Adults $\geq$ 12 years old.
<b>Coverage Duration</b>	<b>Initial:</b> six months. <b>Reauthorization:</b> 12 months.  Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.
<b>Other Criteria (LCD, NCD, etc.)</b>	None.
<b>Misc Info, Appendix Etc.</b>	None.

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	1/26/26	1/26/26	Tamara Chinarian, PharmD, Clinical Pharmacist	N/A
Approved	N/A	2/12/26	Pharmacy & Therapeutics (P&T) Committee	2/12/26