

PA Criteria	Criteria Details
Covered Uses (FDA approved indication)	Nucala is an interleukin-5 (IL-5) antagonist indicated for several conditions including severe eosinophilic asthma, eosinophilic granulomatosis with polyangiitis (EGPA) and hypereosinophilic syndrome (HES).
Exclusion Criteria	Must not be used in combination with other biologic drugs.
Required Medical Information	<p>For initial coverage of severe eosinophilic asthma:</p> <ol style="list-style-type: none"> 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided - AND - 2. Must have an elevated eosinophil level greater than or equal to 150 cells/mcL within six weeks (prior to the immediate start of treatment with Nucala) - OR - greater than or equal to 300 cells/mcL in the previous 12 months - AND - 3. Must try and fail 1 ICS/LABA inhaler drug in the past six months (fail is defined as an intolerance or inability to improve the condition on required therapy for at least four weeks). <p>For reauthorization requests for severe eosinophilic asthma:</p> <ol style="list-style-type: none"> 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. 2. Must have clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in oral steroid use). <p>For initial coverage of Hypereosinophilic Syndrome (HES):</p> <ol style="list-style-type: none"> 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. 2. Must have a blood eosinophil count at least 1,000 cells/mcL. 3. Must have had HES for at least six months. 4. Must have had at least two flares of HES in the past year defined as symptoms requiring a steroid or increase in current steroid. 5. The provider attests that there is NO identifiable non-hematologic secondary cause of HES. 6. Must try and fail (defined as an inability to improve symptoms) a generic steroid- sparing drug (e.g., methotrexate, hydroxyurea). <p>For reauthorization requests for Hypereosinophilic Syndrome (HES):</p> <ol style="list-style-type: none"> 1. Medical records supporting the request, including documentation of prior therapies and responses to treatment must be provided. 2. Must have clinical benefit (e.g., decrease in exacerbations, improvement in symptoms, decrease in steroid use).
Age Restriction	None.
Prescriber Restrictions	Prescriber is a specialist or has consulted with a specialist for the condition being treated.
Coverage Duration	Initial: one year; reauthorization: two years. Dose will be approved according to the FDA approved labeling or within accepted standards of medical practice.

Other Criteria/Information	Refer to the Gold Coast Health Plan Medicare Part B Reference and Summary of Evidence document.		
	HCPCS	Description	Billing Units/How Supplied
	J2182	Nucala (mepolizumab) Vial	Billing unit: 1 mg 100mg SDV

STATUS	DATE REVISED	REVIEW DATE	APPROVED/REVIEWED BY	EFFECTIVE DATE
Created	3/26/2025	3/26/2025	Dawn Shojai, PharmD, Senior Pharmacy Benefit Consultant (PSG)	N/A
Approved	N/A	8/21/2025	Pharmacy & Therapeutics (P&T) Committee	8/21/2025