GCHP Medi-Cal Clinical Guidelines
Mepolizumab (Nucala™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	• Add-on maintenance treatment of severe asthma in adults and pediatric patients ≥ 6 years of age with an eosinophilic phenotype. • Treatment of adults with eosinophilic granulomatosis with polyangiitis (EGPA or Churg-Strauss Syndrome) • Treatment of adults and pediatric patients ≥ 12 years of age with hypereosinophilic syndrome for > six months without an identifiable nonhematologic secondary cause. • Add-on maintenance treatment of chronic rhinosinusitis with nasal polyps in adults with an inadequate response to nasal corticosteroids
Exclusion Criteria	• When used as monotherapy (mepolizumab is an add on therapy to the current asthma treatment regimen). • When used concurrently with other monoclonal antibodies with similar indications such as benralizumab, dupilumab, omalizumab, reslizumab or Tezepelumab. • Subcutaneous injection for home administration by self or caregiver (submitted to MediCalRx).
Required Medical Information	Dosage form that is being requested for administration during the medical visit (Pen vs. Syringes vs. Vials) ▪ Nucala™ Autoinjector pen and Prefilled syringes: FDA approved for self or caregiver administration with proper training. ▪ Nucala™ Vials: FDA approved for administration by health care provider. **Asthma** • Eosinophilic phenotype defined as blood eosinophils ≥ 300 cells/uL within previous 12 months or ≥ 150 cells/uL within last 6 weeks AND • Inadequate asthma control (for example, hospitalization or emergency medical care visit within the past year) despite current treatment with both of the following medications at optimal dosage: i. inhaled corticosteroid; AND ii. long acting beta2-agonits, leukotriene modifier or sustained release theophylline **EGPA** • History or the presence of an eosinophilic count > 1,000 cells/uL or blood eosinophilic level of higher than 10% AND • 2 or more of the following disease characteristics of EGPA: i. Biopsy showing histopathological evidence of eosinophilic vasculitis, perivascular eosinophilic infiltration or eosinophil-rich granulomatous inflammation ii. Neuropathy

	iii. Pulmonary infiltrates iv. Sinonasal abnormalities v. Cardiomyopathy vi. Glomerulonephritis vii. Alveolar hemorrhage viii. Palpable purpura ix. Antineutrophil cytoplasmic antibody (ANCA) positivity AND • At least one relapse (requiring increase in oral corticosteroids dose initiation / increased dose of immunosuppressive therapy or hospitalization) within two years prior to starting treatment with mepolizumab (Nucala) or has a refractory disease. **Chronic Rhinosinusitis with Nasal Polyps (CRSwNP)** • History of prior nasal poly removal surgery along with date of procedure. • Treatment failure with ≥ eight weeks of nasal corticosteroids. **Hypereosinophilic syndrome (HES)** • Clinical notes confirming the diagnosis of HES ≥ six months • Clinical notes indicating that secondary potential causes of non-hematologic eosinophilia have been ruled out such as but not limited to: i. FIP1L1-PDGFRα kinase positive ii. Parasitic helminth infection iii. Drug hypersensitivity iv. HIV infection v. Non-hematologic malignancy • Signs and symptoms of organ involvement • At least two HES flares within the past 12 months • Current lab report with absolute eosinophil count (AES) ≥ 1,500 cells/uL • Documentation of failure to induce remission with a corticosteroid (first-line therapy) • Documentation of failure to induce remission with hydroxyureas or imatinib (Gleevec)
Age Restriction	Asthma: 6 years of age and older. EGPA & CRSwNP: 18 years of age and older. Hypereosinophilic syndrome: 12 years of age and older.
Prescriber Restrictions	None.
Coverage Duration	**Vials**: 1 dose to allow administration of starting dose with the goal of transitioning to the autoinjector pen or prefilled syringe for maintenance treatment at home (provided by the pharmacy).
Other Requirements & Information	Criteria adapted from DHCS March 2024. Mepolizumab (Nucala™) is available for self-administration in the form of an autoinjector and a prefilled syringe, which are typically administered by the

member or a caregiver at home. Nucala™ autoinjector or prefilled syringes should be provided to the member by a pharmacy through pharmacy benefit.

Vials: Requests will be approved up to one month, if the health care provider prefers to administer the first dose for new start requests, by obtaining it though the practice until safety is determined.

If administration by the provider is requested beyond the time frames shown above, the provider must include reason(s) on the renewal referral stating why the member or caregiver cannot obtain the drug through the pharmacy benefit for self- or caregiver administration.

HCPCs	Description	Dosing, Units
J2182	Injection, mepolizumab, per 1mg (Nucala™ Autoinjector Pen & Prefilled syringe)	Asthma • ≥ 12 years: 100 mg (100 units) subcutaneously (SC) every four weeks. • 6-11 years: 40 mg (400 units) SC every four weeks.
		EGPA: ≥ 18 years: 300 mg (300 units) SC every four weeks.
		HES: ≥ 12 years: 300 mg (300 units) SC every four weeks.
		CRSwNP: ≥ 18 years: 100 mg (100 units) SC every four weeks.
		Maximum Dose: 300 mg (300 HCPCS units per service date)

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	5/1/2024	5/1/2024	Yoonhee Kim, Clinical Programs Pharmacist Lily Yip, Director of Pharmacy Services	N/A
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