mepolizumab (Nucala®)

Commercial Pharmacy Benefit Drug Policy

Drug Details

USP Category: RESPIRATORY TRACT/PULMONARY AGENTS

Mechanism of Action: interleukin-5 (IL-5) antagonist monoclonal antibody that reduces the production and survival of eosinophils

Label Name	Quantity Limit
Nucala 100 MG/ML SOLN A-INJ	3 auto-injectors/28 days
Nucala 40 MG/0.4ML SOLN PRSYR	1 syringe/28 days
Nucala 100 MG/ML SOLN PRSYR	3 syringes/28 days

Condition(s) listed in policy *(see coverage criteria for details)*

- Chronic rhinosinusitis with nasal polyposis (CRSwNP)
- Eosinophilic granulomatosis with polyangiitis (EGPA) - formerly known as Churg-Strauss syndrome
- Hypereosinophilic syndrome (HES)
- Severe eosinophilic asthma

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

The following condition(s) require Prior Authorization/Preservice:

Chronic rhinosinusitis with nasal polyposis (CRSwNP)

1. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist, **and**
2. Patient has nasal polyps, **and**
3. Patient is at least 18 years old, **and**
4. Inadequate response, intolerable side effect, or contraindication to an intranasal glucocorticoid **and**
5. Dose does not exceed 100 mg given SQ every 4 weeks.

Coverage Period:
1 year

Eosinophilic granulomatosis with polyangiitis (EGPA) - formerly known as Churg-Strauss syndrome

Initial Request
1. Patient is at least 18 years old, **and**
2. Prescribed by or in consultation with an immunologist, **and**
3. Patient has relapsing or refractory disease despite treatment with oral corticosteroid (e.g. prednisone, prednisolone) OR immunosuppressive therapy (e.g. azathioprine, methotrexate, mycophenolate mofetil), **and**
4. Dose does not exceed 300 mg given SQ every 4 weeks.

Reauthorization
1. Provider attestation that patient is responding to Nucala, **and**
2. Dose does not exceed 300 mg given SQ every 4 weeks.

Covered Doses:
Initial: 6 months
Reauthorization: 1 year

Coverage Period:

Hypereosinophilic syndrome (HES)
1. Prescribed by or in consultation with an allergist or immunologist or hematologist, **and**
2. Patient is negative for FIP1-like 1-platelet derived growth factor receptor (FIP1L1-PDGFR) gene mutation, **and**
3. Patient is at least 12 years of age, **and**
4. Inadequate response to oral corticosteroids (e.g. prednisone) or hydroxyurea, **and**
5. Dose does not exceed 300 mg given SQ every 4 weeks.

Coverage Period:
1 year

Severe eosinophilic asthma
Initial Request
1. Patient is at least 6 years old, **and**
2. Prescribed by or in consultation with a pulmonologist, allergist, or immunologist, **and**
3. Eosinophil blood count of $\geq$ 150 cells/μL within last 6 weeks or $\geq$ 300 cells/μL within the last 12 months, **and**
4. Asthma symptoms remain uncontrolled despite 3 months of treatment with a high-dose inhaled corticosteroid (ICS) in combination with long-acting beta agonist (LABA) or leukotriene receptor antagonists (e.g. montelukast, zafirlukast, zileuton) , **and**
5. Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment (e.g. Cinqair, Dupixent, Fasenra, Xolair, Tezspire), **and**
6. Dose does not exceed 100 mg given SQ every 4 weeks, **and**
7. Meets ONE of the following within the past year:

- One or more acute asthma attacks requiring emergency care, or
- One or more acute inpatient visits where asthma was the principal diagnosis, or
- Use of chronic systemic steroids due to severe asthma OR two or more acute asthma exacerbations requiring oral systemic steroids.

Reauthorization
1. Patient is not receiving this medication in combination with another biologic medication indicated for asthma treatment (e.g. Cinqair, Dupixent, Nucala, Xolair, Tezspire), **and**
2. Dose does not exceed 100 mg given SQ every 4 weeks, **and**
3. Asthma symptoms have improved or controlled while on Nucala.

Coverage Period:
Initial: 6 months
Reauthorization: 1 year

Additional Information
- Dosing and administration for asthma:
  - Severe asthma in patients aged 12 years and older: 100 mg administered subcutaneously once every 4 weeks.
  - Severe asthma in patients aged 6 to 11 years: 40 mg administered subcutaneously once every 4 weeks.
- Table 1: Inhaled Corticosteroid (ICS) & Long-Acting Beta-Agonist (LABA) Agents

Agent	ICS	LABA (+LAMA)
combination inhalers		
Symbicort	budesonide	formoterol
Breo Ellipta	fluticasone	vilanterol
Advair Diskus, Advair HFA, Wixela Inhub	fluticasone	salmeterol
AirDuo Respiclick, AirDuo Digihaler	fluticasone	salmeterol
Dulera	mometasone	formoterol
Trelegy Ellipta	fluticasone	vilanterol (+ umeclidinium)
separate inhalers		
Alvesco	ciclesonide	
Arnuity Ellipta	fluticasone	
Asmanex, Asmanex HFA	mometasone	
Flovent Diskus, Flovent HFA, Armonair Digihaler	fluticasone	

Pulmicort Flexhaler	budesonide	
Qvar Redihaler	beclomethasone	
Serevent		salmeterol

- Table 2. Intranasal Glucocorticoids

flunisolide (Nasarel) fluticasone (Flonase) mometasone (Nasonex) fluticasone/azelastine (Dymista) Xhance (fluticasone EDS) Omnaris (ciclesonide) Beconase AQ (beclomethasone) Qnasl (beclomethasone) Veramyst (fluticasone) Zetonna (ciclesonide) Dymista (fluticasone/azelastine) Nasonex (mometasone) Nasacort AQ (triamcinolone) Rhinocort Aqua (budesonide)

References

1. Prescribing Information. Nucala. GlaxoSmithKline Inc. 3/2023
2. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention (2023 Update). Available from: www.ginasthma.org
3. AHFS®. Available by subscription at http://www.lexi.com
4. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
5. Long-Acting Beta-Agonists (LABAs) | AAAAI
6. Inhaled Corticosteroids | AAAAI

Review History

Date of Last Annual Review: 1Q2024
Date of last revision: 02/28/2024
Changes from previous policy version:

- Clarify specialist requirement for HES indication

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee