

**NATL**

Coverage of drugs is first determined by the member's pharmacy or medical benefit. Please consult with or refer to the Evidence of Coverage document.

**I. FDA Approved Indications:**

- Nucala is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma aged 12 years and older, and with an eosinophilic phenotype.

**II. Health Net Approved Indications and Usage Guidelines:**

- Diagnosis of severe asthma (see General Information) in patients ≥ 12 years old  
AND
- Prescribed by a Pulmonologist or Allergist  
AND
- Use of an inhaled or oral corticosteroid AND a long-acting beta-agonist (LABA). If a long-acting beta-agonist is contraindicated, a second controller agent must be used in combination with an inhaled corticosteroid. Patients must be compliant with controller medication therapy.  
AND
- Patient has a blood eosinophil count of greater than or equal to 150 cells/mcL within the past 3 months  
AND
- Patient experiences two (2) exacerbations requiring a course of oral/systemic corticosteroids (or increase in dose if already on oral corticosteroid), hospitalization or an emergency room visit in a twelve (12) month period; or one exacerbation requiring intubation

**III. Coverage is Not Authorized For:**

- Non-FDA approved indications, which are not listed in the Health Net Approved Indications and Usage Guidelines section, unless there is sufficient documentation of efficacy and safety in the published literature.

**IV. General Information:**

- Nucala is not indicated for treatment of other eosinophilic conditions or relief of acute bronchospasm or status asthmaticus.
- The pivotal trials defined severe asthma as 2 or more exacerbations of asthma despite regular use of high-dose inhaled corticosteroids plus an additional controller with or without oral corticosteroids. Clinically significant exacerbation was defined as a worsening of asthma leading to the doubling (or more) of the existing maintenance dose of oral glucocorticoids for 3 or more days or hospital admission or an emergency department visit for asthma treatment.
- Controller medications are: inhaled glucocorticoids (Flovent, Pulmicort, Qvar, Asmanex), long-acting beta-agonists (LABAs) such as salmeterol, formoterol, or vilanterol, and antileukotriene agents (montelukast [Singular®], zafirlukast [Accolate®] or Zyflo® [zileuton]). Theophylline is also a controller agent, however, it is not as efficacious as LABAs.

**Prior Authorization Protocol**  
**NUCALA<sup>®</sup> (mepolizumab)**

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- Patients could potentially meet criteria for both Xolair and Nucala. The combination has not been studied. Approximately 30% of patients in the MENSA study also were candidates for therapy with Xolair.

**V. Therapeutic Alternatives:**

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Dose/Limit/Maximum Dose</b>
<i>Inhaled corticosteroids</i>		
Beclomethasone (Qvar <sup>®</sup> )	40 mcg, 80 mcg/actuation 1-4 actuations BID	4 actuations BID
Budesonide (Pulmicort <sup>®</sup> )	200 mcg/actuation 1-2 actuations QD or BID	2 actuations BID
Alvesco <sup>®</sup> (ciclesonide)	80 mcg, 160 mcg per actuation 1-2 actuations BID	2 actuations BID
Aerospan <sup>®</sup> (flunisolide)	80 mcg per actuation 1-2 actuations BID	2 actuations BID
Flovent <sup>®</sup> (fluticasone propionate)	44-250 mcg per actuation 1-2 actuations BID	2 actuations BID
Arnuity Ellipta <sup>®</sup> (fluticasone furoate)	100 mcg, 200 mcg per actuation 1 actuation QD	1 actuation QD
Asmanex <sup>®</sup> (mometasone)	110 mcg, 220 mcg 1-2 inhalations QD to BID	2 inhalations BID
<i>Long-acting beta-agonists</i>		
Foradil <sup>®</sup> (formoterol)	12 mcg capsule for inhalation 1 capsule BID	24 mcg per day
Serevent <sup>®</sup> (salmeterol)	5 mcg per dose 1 inhalation BID	1 inhalation BID
<i>Combination products</i>		
Dulera <sup>®</sup> (mometasone/formoterol)	100/5 mcg, 200/5 mcg per actuation 2 actuations BID	4 actuations per day
Breo Ellipta <sup>®</sup> (fluticasone/vilanterol)	100/25 mcg, 200/25 mcg per actuation 1 actuation QD	1 actuation QD
Advair <sup>®</sup> (fluticasone/salmeterol)	100/50 mcg, 250/50 mcg, 500/50 mcg per actuation 1 actuation BID	1 actuation BID
Symbicort <sup>®</sup> (budesonide/formoterol)	80 mcg/4.5 mcg; 160 mcg/4.5 mcg per actuation 1-2 actuations BID	2 actuations BID

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<b>Drug</b>	<b>Dosing Regimen</b>	<b>Dose/Limit/Maximum Dose</b>
<i>Antileukotriene agents</i>		
Montelukast (Singulair®)	4 to 10 mg PO QD	10 mg per day
Zafirlukast (Accolate®)	10 to 20 mg PO BID	40 mg per day
Zyflo® (zileuton)	1200 mg PO BID	2400 mg per day
<i>Oral glucocorticoids</i>		
Dexamethasone (Decadron)	0.75 to 9 mg/day PO in 2 to 4 divided doses	Varies
Methylprednisolone (Medrol)	40 to 80 mg PO in 1 to 2 divided doses	Varies

\*Requires Prior Authorization

**VI. Recommended Dosing Regimen and Authorization Limit:**

<b>Drug</b>	<b>Dosing Regimen</b>	<b>Authorization Limit</b>
Nucala	100 mg SC every 4 weeks	3 months initial authorization If documentation by medical records of a reduction in asthma exacerbation is provided, then renew for 6 months or to member's renewal period, whichever is longer

**VII. Product Availability:**

Vial: 100 mg of lyophilized powder in a single-dose vial for reconstitution

**VIII. References:**

1. Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline; November 2015.
2. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. N Engl J Med 2014;371:1198-207.
3. Bel EH, Wenzel SE, Thompson PH, et al. Oral glucocorticoid-sparing effect of mepolizumab in eosinophilic asthma. New Engl J Med 2014;371:1189-97.
4. Pavord ID, Korn S, Howarth P et al. Mepolizumab for severe eosinophilic asthma (DREAM): a multicenter, double-blind, placebo-controlled trial (Abstract). Lancet 2012;380(9842):651-59.

*The materials provided to you are guidelines used by this health plan to authorize, modify, or determine coverage for persons with similar illnesses or conditions. Specific care and treatment may vary depending on individual needs and the benefits covered under your contract.*