

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**                      **NUCALA**  
**(generic)**                              **(mepolizumab)**

**Status: CVS/caremark Criteria**  
**Type: Initial Prior Authorization**

**Med D**  
**Ref # 1302-A**

**FDA-APPROVED INDICATIONS<sup>1</sup>**

Maintenance Treatment of Severe Asthma

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.

*Limitations of Use:* Not for relief of acute bronchospasm or status asthmaticus

Eosinophilic Granulomatosis with Polyangiitis

Nucala is indicated for the treatment of adult patients with eosinophilic granulomatosis with polyangiitis (EGPA).

**CRITERIA FOR APPROVAL**

1	Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype (i.e., eosinophilic asthma)? [If no, skip to question 7.]	Yes	No
2	Is this a request for continuation of therapy with Nucala? [If yes, skip to question 5.]	Yes	No
3	Is the patient's baseline eosinophil blood count greater than or equal to 150 cells per microliter? [If no, no further questions.]	Yes	No
4	Does the patient have a history of severe asthma attacks (exacerbations) despite treatment with both of the following medications at optimized doses: 1) inhaled corticosteroid, AND 2) additional controller (long acting beta <sub>2</sub> -agonist, leukotriene modifier, or sustained-release theophylline)? [If yes, skip to question 6.] [If no, no further questions.]	Yes	No
5	Has the patient's asthma control improved on Nucala treatment, demonstrated by a reduction in the frequency or severity of symptoms and exacerbations or a reduction in the daily maintenance oral corticosteroid dose? [If no, no further questions.]	Yes	No
6	Is the patient 12 years of age or older? [No further questions.]	Yes	No
7	Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA)? [If no, no further questions.]	Yes	No
8	Is this a request for continuation of therapy with Nucala? [If yes, skip to question 10.]	Yes	No

9	Does the patient have a history or the presence of an eosinophil blood count of more than 1000 cells per microliter or a blood eosinophil level of greater than 10 percent? [If yes, skip to question 11.] [If no, no further questions.]	Yes	No
10	Has the patient had a beneficial response to treatment with Nucala, demonstrated by any of the following: 1) a reduction in the frequency of relapses, 2) a reduction in the daily oral corticosteroid dose, or 3) no active vasculitis? [If no, no further questions.]	Yes	No
11	Is the patient 18 years of age or older?	Yes	No

Guidelines for Approval			
Duration of Approval		12 months	
Set 1: Asthma, initial therapy		Set 2: Asthma, continuation of therapy	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
1	2	1	None
3		2	
4		5	
6		6	
Set 3: EGPA, initial therapy		Set 4: EGPA, continuation of therapy	
Yes to question(s)	No to question(s)	Yes to question(s)	No to question(s)
7	1	7	1
9	8	8	
11		10	
		11	

Internal Use Only – Mapping Instructions			
	Yes		No
1.	Go to 2		Go to 7
2.	Go to 5		Go to 3
3.	Go to 4		Deny
4.	Go to 6		Deny
5.	Go to 6		Deny
6.	Approve 12 months		Deny
7.	Go to 8		Deny
8.	Go to 10		Go to 9
9.	Go to 11		Deny
10.	Go to 11		Deny
11.	Approve 12 months		Deny

**RATIONALE**

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

## REFERENCES

1. Nucala [package insert]. Research Triangle Park, NC: GlaxoSmithKline, Inc.; December 2017.
2. Ortega HG, Liu MC, Pavord ID, et al. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Eng J Med.* 2014;371:1198-1207.
3. Bel EH, Wenzel SE, Thompson PJ, et al. Oral glucocorticoid-sparing effect of mepolizumab in eosinophilic asthma. *N Eng J Med.* 2014;371:1189-1197.
4. Global Initiative for Asthma (GINA). Global Strategy for Asthma Management and Prevention. 2017 update. <http://ginasthma.org/2017-gina-report-global-strategy-for-asthma-management-and-prevention/>. Accessed March 3, 2017.
5. Wechsler ME, Akuthota P, Jayne D, et al. Mepolizumab or placebo for eosinophilic granulomatosis with polyangiitis. *N Engl J Med.* 2017;18;376(20):1921-1932.

## DOCUMENT HISTORY

Written: Specialty Clinical Development (KF) 11/2015  
Revised: KF 06/2016 (CMS), LP 03/2017 (CMS) IP 12/2017 (label update. EGPA)  
Reviewed: CDPR/ DNC 11/2015, ME 03/2017; DNC 12/2017  
External Review: 11/2015, 05/2017