

PRIOR AUTHORIZATION CRITERIA

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

Status: CVS/caremark Criteria
Type: Initial Prior Authorization

Med D
Ref # 1302-A

FDA-APPROVED INDICATIONS¹

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 ₂ -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