



## NHS MEDICAL POLICY

### Interleukin-5 (IL-5) Receptor Antagonist Therapy for Asthma Medicine 2016-002

- A. Monoclonal antibodies directed against interleukin-5 (IL-5) are used as therapeutic agents for severe eosinophilic asthma or eosinophilic granulomatosis with polyangiitis (EGPA).**

**For initiation of anti-IL-5 therapy, please use current MCG.**

**Benralizumab (A-0985)**

**Reslizumab (A-0942)**

**Mepolizumab (A-0922)**

- B. For continuation of anti-IL-5 therapy, ALL the following must be present:**

1	Only ONE of the following interleukin-5 receptor antagonists is to be used at a time: <ul style="list-style-type: none"><li>• Mepolizumab (Nucala)</li><li>• Reslizumab (Cinqair)</li><li>• Benralizumab (Fasenra)</li></ul>
2	Continuation of the IL-5 receptor antagonist is by or in consultation with ONE of the following types of physicians: <ul style="list-style-type: none"><li>• Pulmonologist</li><li>• Allergist/Immunologist</li></ul>
3	The IL-5 receptor antagonist is prescribed no more frequently than every 4 weeks.

4	The provider has documented tolerance with no adverse reactions to the IL-5 receptor antagonist.
5	<p>The provider has documented evidence of a positive clinical response to treatment, as indicated by ONE or more of the following:</p> <ul style="list-style-type: none"> <li>• A reduction in asthma symptoms</li> <li>• A reduction in frequency of asthma exacerbations</li> <li>• Reduced use of controller medications</li> <li>• Increased FEV1 from pretreatment baseline</li> </ul>
6	<p>The member still requires ongoing treatment with BOTH of the following:</p> <ul style="list-style-type: none"> <li>• High-dose inhaled corticosteroid (<i>listed in Appendix A</i>)</li> <li>• One additional asthma control medication (<i>listed in section A, #10</i>)</li> </ul>

## SOURCES

1. U.S. Food and Drug Administration (FDA). FDA approves Nucala to treat severe asthma. FDA Press Release. Silver Spring, MD: FDA; November 4, 2015.
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3. Chung KF, Wenzel SE, Brozek JL, et al. International ERS/ATS guidelines on definition, evaluation and treatment of severe asthma. *Eur Respir J*. 2014;43(2):343-373.
4. Dweik RA, et al. An Official ATS (American Thoracic Society) Clinical Practice Guideline: Interpretation of Exhaled Nitric Oxide Levels (FENO) for Clinical Applications, *Am J Respir Crit Care Med* Vol 184. pp 602–615, 2011.
5. Gotlib J. World Health Organization-defined eosinophilic disorders: 2015 update on diagnosis, risk stratification, and management. *Am J Hematol*. 2015;90(11):1077-1089.
6. Nair P. Anti-interleukin-5 monoclonal antibody to treat severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1249-1251.
7. Ortega HG, Liu MC, Pavord ID, et al.; MENSA Investigators. Mepolizumab treatment in patients with severe eosinophilic asthma. *N Engl J Med*. 2014;371(13):1198-1207.
8. Pavord ID, Korn S, Howarth P, et al. Mepolizumab for severe eosinophilic asthma (DREAM): A multicentre, double-blind, placebo-controlled trial. *Lancet*. 2012;380(9842):651-659.
9. Powell C, Milan SJ, Dwan K, et al. Mepolizumab versus placebo for asthma. *Cochrane Database Syst Rev*. 2015;7:CD010834.
10. Walford HH, Doherty TA. Diagnosis and management of eosinophilic asthma: a US perspective, *J Asthma Allergy*, 2014;7 53–65
11. American College of Physicians, Medical Knowledge Self-Assessment Program (MKSAP 17) Chapter 02: Airways Disease
12. UpToDate.com was accessed Jun 5, 2018: Treatment of severe asthma in adolescents and adults
13. Milliman Care Guidelines, 24<sup>th</sup> edition was accessed May 28, 2020.

**CODE REFERENCE** (This may not be a comprehensive list of codes to apply to this policy.)

C9473, J2182, J2786, J3590, 96372, 96401

**POLICY HISTORY/REVISION INFORMATION**

Date	Action/Description
12/13/2017	Annual renewal and approval by UM Committee
06/13/2018	Added Benralizumab (Fasenra) to A: Lines 1 & 4 and B: Line 1; Sources; added lines 12 & 13; Code References added J2182, J2786 & J3590
06/12/2019	Annual renewal and approval by UM Committee
06/11/2020	This was altered to suggest simply using MCG criteria for initial treatment and using the NHS policy for continued treatment. MCG does not address continued treatment.
06/11/2021	Annual renewal and approval by UM Committee
06/10/2022	Annual renewal and approval by UM Committee
05/26/2023	Annual review and approval by UM/QM Committee
05/20/2024	Annual review and approval by UM/QM Committee
03/24/2025	Annual review and approval by UM/QM Committee

## Appendix A: Estimated Comparative Daily Doses for Inhaled Glucocorticoids

From UpToDate.com, National Heart, Blood, and Lung Institute Expert Panel Report 3 (EPR 3): Guidelines for the Diagnosis and Management of Asthma; 2007.

Drug	Low dose	Medium dose	High dose
<b>Beclomethasone HFA</b> (Qvar product available in United States)*	80 to 160 mcg	>160 to 320 mcg	>320 mcg
40 mcg per puff	2 to 4 puffs	¶	¶
80 mcg per puff	1 to 2 puffs	3 to 4 puffs	>4 puffs
<b>Beclomethasone HFA</b> (Qvar product available in Canada, Europe, and elsewhere)	100 to 200 mcg	>200 to 400 mcg	>400 mcg
50 mcg per puff	2 to 4 puffs	¶	¶
100 mcg per puff	1 to 2 puffs	3 to 4 puffs	>4 puffs
<b>Budesonide DPI</b> (Pulmicort Flexhaler product available in United States)*	180 to 360 mcg	>360 to 720 mcg	>720 mcg
90 mcg per inhalation	2 to 4 inhalations	¶	¶
180 mcg per inhalation	1 to 2 inhalations	3 to 4 inhalations	>4 inhalations
<b>Budesonide DPI</b> (Pulmicort Turbuhaler product available in Canada, Europe, and elsewhere)	200 to 400 mcg	>400 to 800 mcg	>800 mcg
100 mcg per inhalation	2 to 4 inhalations	¶	¶
200 mcg per inhalation	1 to 2 inhalations	3 to 4 inhalations	
400 mcg per inhalation	1 inhalation	2 inhalations	>2 inhalations
<b>Ciclesonide HFA</b> (Alvesco product available in United States, Europe, and elsewhere)*	80 to 160 mcg	>160 to 320 mcg	>320 mcg
80 mcg per puff	1 to 2 puffs	3 to 4 puffs	¶
160 mcg per puff	1 puff	2 puffs	>2 puffs
<b>Ciclesonide HFA</b> (Alvesco product available in Canada)	100 to 200 mcg	>200 to 400 mcg	>400 mcg
100 mcg per puff	1 to 2 puffs	3 to 4 puffs	¶
200 mcg per puff	1 puff	2 puffs	>2 puffs
<b>Flunisolide MDI</b> (Aerospin product available in United States)*	320 mcg	>320 to 640 mcg	Insufficient data
80 mcg per puff	4 puffs	5 to 8 puffs	Insufficient data
<b>Fluticasone propionate HFA</b> (Flovent HFA product available in United States)*	88 to 220 mcg	>220 to 440 mcg	>440 mcg
44 mcg per puff	2 to 5 puffs	¶	¶
110 mcg per puff	1 to 2 puffs	3 to 4 puffs	
220 mcg per puff	Δ	2 puffs	>2 puffs
<b>Fluticasone propionate HFA</b> (Flovent HFA product available in Canada, Europe, and elsewhere)	100 to 250 mcg	>250 to 500 mcg	>500 mcg
50 mcg per puff	2 to 5 puffs	¶	¶
125 mcg per puff	1 to 2 puffs	3 to 4 puffs	
250 mcg per puff	Δ	2 puffs	>2 puffs
<b>Fluticasone propionate DPI</b> (Flovent Diskus product available in United States and Canada)*	100 to 250 mcg	>250 to 500 mcg	>500 mcg
50 mcg per inhalation	2 to 5 inhalations	¶	¶
100 mcg per inhalation	1 to 2 inhalations	3 to 5 inhalations	
250 mcg per inhalation	1 inhalation	2 inhalations	>2 inhalations
500 mcg per inhalation (strength not available in United States)	Δ	1 inhalation	>1 inhalation
<b>Fluticasone furoate DPI</b> (Arnuity Ellipta product available in United States)* NOTE: Inhaled fluticasone furoate has a greater anti-inflammatory potency per microgram than fluticasone propionate inhalers. Thus, fluticasone furoate is administered at a lower daily dose and used only once daily.	Not available for low dose	100 mcg	200 mcg
100 mcg per inhalation	Low dose not available in this preparation	1 inhalation	2 inhalations
200 mcg per actuation	Low dose not available in this preparation	Δ	1 inhalation
<b>Mometasone DPI</b> (Asmanex DPI product available in United States)*	110 to 220 mcg	>220 to 440 mcg	>440 mcg
110 mcg per inhalation	1 to 2 inhalations	¶	¶
220 mcg per inhalation	1 inhalation	2 inhalations	>2 inhalations
<b>Mometasone HFA</b> (Asmanex HFA product available in United States)*	100 to 200 mcg	>200 to 400 mcg	>400 mcg
100 mcg per actuation	1 to 2 inhalations	¶	¶
200 mcg per actuation	1 inhalation	2 inhalations	>2 inhalations
<b>Mometasone DPI</b> (Asmanex Twisthaler product available in Canada, Europe, and elsewhere)	200 mcg	>200 to 400 mcg	>400 mcg
200 mcg per inhalation	1 inhalation	2 inhalations	>2 inhalations
400 mcg per inhalation	Δ	1 inhalation	>1 inhalation