Effective Date: 12/14/16



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 of the following must be present:

- Only ONE of the following interleukin-5 receptor antagonists is to be used at a time:
 - Mepolizumab (Nucala)
 - Reslizumab (Cinqair)
 - Benralizumab (Fasenra)
- 2 Continuation of the IL-5 receptor antagonist is by or in consultation with ONE of the following types of physicians:
 - Pulmonologist
 - Allergist/Immunologist
- 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.
- The provider has documented evidence of a positive clinical response to treatment, as indicated by ONE or more of the following:
 - A reduction in asthma symptoms
 - A reduction in frequency of asthma exacerbations
 - Reduced use of controller medications
 - Increased FEV1 from pretreatment baseline
- 6 The member still requires ongoing treatment with BOTH of the following:
 - High-dose inhaled corticosteroid (listed in Appendix A)
 - One additional asthma control medication (listed in section A, #10)

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.
- 2. Bel EH, Wenzel SE, Thompson PJ, et al.; SIRIUS Investigators. Oral glucocorticoid-sparing effect of mepolizumab in eosinophilic asthma. N Engl J Med. 2014;371(13):1189-1197.
- 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, 24th 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		
	Added Benralizumab (Fasenra) to A: Lines 1 & 4 and B: Line 1; Sources;		
06/13/2018	added lines 12 & 13; Code References added J2182, J2786 & J3590		
06/12/2019	Annual renewal and approval by UM Committee		
	This was altered to suggest simply using MCG criteria for initial		
	treatment and using the NHS policy for continued treatment.		
06/11/2020	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		

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
Beclomethasone HFA (Ovar product available in United States)*	80 to 160 mcg	>160 to 320 mcg	>320 mcg
40 mcg per puff	2 to 4 puffs	1	1
80 mcg per puff	1 to 2 puffs	3 to 4 puffs	>4 puffs
Beclomethasone HFA	100 to 200 mcg	>200 to 400 mcg	>400 mcg
(Qvar product available in Canada, Europe, and elsewhere)	2 to 4 suffs		
50 mcg per puff	2 to 4 puffs	¶	1 >4 puffs
100 mcg per puff Budesonide DPI	1 to 2 puffs 180 to 360 mcg	3 to 4 puffs >360 to 720 mcg	>4 puffs >720 mcg
(Pulmicort Flexhaler product available in United States)*			
90 mcg per inhalation	2 to 4 inhalations	1	1
180 mcg per inhalation	1 to 2 inhalations	3 to 4 inhalations	>4 inhalations
Budesonide DPI (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	1	1
200 mcg per inhalation	1 to 2 inhalations	3 to 4 inhalations	
400 mcg per inhalation	1 inhalation	2 inhalations	>2 inhalations
Ciclesonide HFA (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	1
160 mcg per puff	1 puff	2 puffs	>2 puffs
Ciclesonide HFA (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	1
200 mcg per puff	1 puff	2 puffs	>2 puffs
Flunisolide MDI (Aerospan 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
Fluticasone propionate HFA (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	1	1
110 mcg per puff	1 to 2 puffs	3 to 4 puffs	
220 mcg per puff	Δ	2 puffs	>2 puffs
Fluticasone propionate HFA (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	n	1
125 mcg per puff	1 to 2 puffs	3 to 4 puffs	
250 mcg per puff	Δ	2 puffs	>2 puffs
Fluticasone propionate DPI (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	1	1
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
Fluticasone furoate DPI (Armuity 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
Mometasone DPI° (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	1	1
220 mcg per inhalation	1 inhalation	2 inhalations	>2 inhalations
Mometasone HFA ° (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	1	1
200 mcg per actuation	1 inhalation	2 inhalations	>2 inhalations
Mometasone DPI° (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