JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS119
		Effective Date	06/11/2019
		Review Date	04/20/2022
	Subject **Self-administered Respiratory Biologics: Nucala, Fasenra Pen**	*Revision Date*	04/20/2022
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Nucala

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I. POLICY

Nucala prefilled autoinjectors and syringes (mepolizumab) and Fasenra Pen (benralizumab) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Nucala** may be approved for patients meeting the following:

1. **Add-on maintenance treatment of severe asthma with an eosinophilic phenotype:**
   a. Documentation has been submitted showing the following:
      I. Patient is 6 years of age or older
      II. Patient has a blood eosinophil count of at least 150 cells/microliter in the past 90 days or 300 cells/microliter in the past 12 months
      III. There is evidence of poorly controlled asthma shown by two or more exacerbations in the past 12 months despite the use of high-dose ICS:
         i. For ages 12-17, ICS dose must be ≥440µg/day fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the mid-strength approved maintenance dose of ICS-LABA combinations
         ii. For 18 years of age and older, ICS dose must be ≥880 mcg/day fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the highest approved maintenance dose of ICS-LABA combinations
      IV. Patient has one of the following:
         i. Prior treatment with at least 2 of the following controllers in addition to an ICS or ICS-LABA combination for at least 6 months and with an adherence rate of 80% or greater:
            1. A long-acting beta agonist [if not already using a ICS-LABA combination]

2. An asthma-indicated long-acting anticholinergic agent
3. A leukotriene modifier
4. theophylline

ii. A documented allergy, contraindication, or an intolerance to any specified prerequisite agent

V. Prescriber is, or has consulted with an Allergist, Immunologist, or Pulmonologist

2. **Treatment of eosinophilic granulomatosis with polyangiitis (EGPA):**
   a. Documentation has been submitted showing the following:
      I. Patient is 18 years of age or older
      II. Patient has had trial and failure, or contraindication with at least one of the following immunosuppressants: azathioprine, cyclophosphamide, or methotexate
      III. Patient is stable on corticosteroids, or has a contraindication to using corticosteroids
      IV. Patient has severe disease (vasculitis with gastrointestinal, cardiac, cerebral, or renal involvement), or symptom recurrence with tapering of corticosteroid therapy
      V. Patient's diagnosis has been confirmed by the history or presence of at least four of the following diagnostic criteria:
         i. asthma
         ii. eosinophilia (>10% eosinophils on the differential leukocyte count)
         iii. biopsy showing evidence of eosinophilic vasculitis
         iv. transient pulmonary infiltrates
         v. mononeuropathy or polyneuropathy
         vi. paranasal sinus abnormalities
      VI. Prescriber is, or has consulted with, an Allergist, Immunologist, Pulmonologist, or Rheumatologist
3. **Add-on maintenance treatment of chronic Rhinosinusitis with Nasal Polyposis (CRSwNP):**
   a. Documentation has been submitted showing the following:
      I. Patient is 18 years of age or older
      II. Patient has a diagnosis of inadequately controlled CRSwNP and any of the following:
         i. nasal congestion and discharge
         ii. breathing difficulties
         iii. reduced or loss sense of smell and taste
         iv. facial pressure
      III. Patient has experienced ONE of the following:
         i. Continued symptoms after sino-nasal surgery
         ii. Trial and inadequate response to one oral corticosteroid and one nasal corticosteroid regimen
4. **Treatment of hypereosinophilic syndrome (HES):**
   a. Documentation has been submitted showing the following:
      I. Patient is 12 years of age or older
      II. Patient has had a diagnosis of HES for 6 months or longer,with a history of two or more flares within the past year
      III. Patient has FIP1L1-PDGFR# kinase-negative disease
      IV. Patient does not have an identifiable non-hematologic secondary cause of HES, such as any of the following:
         i. drug hypersensitivity
         ii. parasitic helminth infection
         iii. HIV infection

iv. non-hematologic malignancy

V. Patient has a blood eosinophil level of ≥ 1,000 cells per microliter prior to treatment

VI. Patient is currently receiving a stable dose of HES therapy, such as one of the following:

i. oral corticosteroid

ii. immunosuppressant

iii. cytotoxic therapy

VII. Prescriber is, or has consulted with, an Allergist, Immunologist, Hematologist, Cardiologist, or Pulmonologist

B. **Fasenra** may be approved for the following:

1. **Add-on maintenance treatment of severe asthma with an eosinophilic phenotype:**

a. Documentation has been submitted showing the following:

I. Patient is 12 years of age or older

II. Patient has a blood eosinophil count of at least 150 cells/microliter in the past 90 days OR 300 cells/microliter in the past 12 months

III. There is evidence of poorly controlled asthma as evidenced by two or more exacerbations in the past 12 months despite the use of high-dose ICS:

i. For ages 12-17, ICS dose must be ≥440µg/day fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the mid-strength approved maintenance dose of ICS-LABA combinations

ii. For 18 years of age and older, ICS dose must be ≥880 mcg/day fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the highest approved maintenance dose of ICS-LABA combinations

IV. Patient has one of the following:

i. Prior treatment with at least 2 of the following controllers in addition to an ICS or ICS-LABA combination for at least 6 months and with an adherence rate of 80% or greater:

1. A long-acting beta agonist [if not already using a ICS-LABA combination]
2. An asthma-indicated long-acting anticholinergic agent
3. A leukotriene modifier
4. theophylline

ii. A documented allergy, contraindication, or an intolerance to any specified prerequisite agent

V. Prescriber is, or has consulted with an Allergist, Immunologist, or Pulmonologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy

B. Continuation of therapy by indication:

1. Continuation of asthma therapy: Approval may be extended in 12-month intervals with documentation showing the patient's clinical improvement from treatment as supported by ONE of the following:
   a. Reduction in asthma symptoms (wheezing, coughing, shortness of breath, chest tightness)
   b. Reduction in administration frequency of short-acting rescue medication
   c. Reduction in exacerbation frequency and asthma-related hospitalizations (no increase in inhaled or oral corticosteroid dose)
   d. Elevation in predicted FEV1 from the patient's baseline before treatment.
2. Continuation of EGPA therapy: Approval may be extended in 6-month intervals with documentation showing the patient's clinical improvement as supported by ONE of the following:
   a. Decrease in maintenance dose of systemic corticosteroids

b. Improvement in BVAS score compared to baseline
c. Improvement in asthma symptoms or exacerbations
d. Patient is in remission, defined as a Birmingham Vasculitis Activity Score (BVAS) score=0 and a prednisone/prednisolone daily dose of less than or equal to 7.5 mg
e. Improvement in duration of remission, or decrease in the rate of relapses

3. Continuation of CRSwNP therapy: Approval may be extended in 12-month intervals with documentation showing the patient has had a positive clinical response to treatment, such as an improved sense of smell, or improved congestion/breathing symptoms
4. Continuation of HES therapy: Approval may be extended in 12-month intervals with documentation showing the patient's clinical improvement as supported by ONE of the following:
   a. Reduction in frequency of HES flares
   b. Maintenance or reduction in background HES therapy usage

C. Patient must be adherent to 80% of prescribed Nucala or Fasenra, as well as other controller medications.

IV. EXCLUSIONS

A. Nucala and Fasenra will not be covered for indications that are not FDA-approved, or guideline-supported.
B. Nucala and Fasenra will not be covered for concurrent use with another biologic.
C. The safety and effectiveness of Nucala has not been established in pediatric patients below 6 years of age for an indication of severe asthma with an eosinophilic phenotype.
D. The safety and effectiveness of Nucala has not been established in patients below 18 years of age for EGPA.
E. The safety and effectiveness of Fasenra has not been established in pediatric patients below 12 years of age for an indication of severe asthma with an eosinophilic phenotype.
F. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information for product-specific dosing details.

VI. REFERENCES

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VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
08/23/2019	Policy Creation
11/26/2019	Clarified Nucala criteria based on new FDA-approval for asthma in pediatric patients 6 years and older
01/15/2020	Added clinical criteria for self- administered Fasenra
01/16/2020	Clarified exclusion criteria regarding concurrent biologic usage
06/05/2020	Minor grammatical changes- no criteria details affected
05/13/2021	Updated authorization guidance
12/08/2021	Updated Exclusions section regarding physician samples
04/20/2022	Updated clinical criteria based on FDA-approved prescribing information

Review/Revision Date:10/16/2019, 11/26/2019, 01/15/2020, 01/16/2020, 06/05/2020, 05/13/2021, 12/08/2021, 04/20/2022