JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Medical Management Drug Policies**	*Policy Number*	MMDP004
		Effective Date	07/16/2014
		Review Date	01/18/2023
	Subject **Provider-administered Respiratory Biologics: Xolair, Nucala, Fasenra**	*Revision Date*	01/18/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

Keywords: Fasenra, Nucala, Xolair

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I. POLICY

A. Xolair (omalizumab), Nucala (mepolizumab), and Fasenra (benralizumab) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

II. POLICY CRITERIA

A. **Xolair** may be approved for the following:

1. **Moderate to severe persistent asthma:**

a. Documentation has been submitted showing the following:

I. Patient is 6 years of age or older

II. Patient has been diagnosed with moderate or severe persistent allergen related asthma (NHLBI criteria)

III. Patient has a documented positive skin test or in vitro reactivity to a perennial aeroallergen

IV. Patient has laboratory results showing a baseline IgE of 30 IU/ml – 700 IU/ml

V. 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 6-11, ICS dose must be ≥352µg/day fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the mid-strength approved maintenance dose of ICS/LABA combinations

ii. 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

iii. 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

VI. 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:

A. A long-acting beta agonist [if not already using a ICS-LABA combination]
B. An asthma-indicated long-acting anticholinergic agent
C. A leukotriene modifier
D. theophylline

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

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

2. **Chronic spontaneous urticaria (CSU):**
   a. Documentation has been submitted showing the following:
      I. Patient is 12 years of age or older
      II. Patient has a history of at least 6 weeks of urticaria
      III. Patient continues to have the presence of hives associated with itching despite adequate trials (a minimum of four weeks each) of the following regimens:
         i. One second generation H1-antihistamine at the recommended standard dose
         ii. At least two of the following:
            A. A second generation H1-antihistamine trialed at two to four times the standard dose
            B. A second generation H1-antihistamine trialed in combination with another second generation H1-antihistamine
            C. A second generation H1-antihistamine in combination with leukotriene antagonist
            D. A second generation H1-antihistamine in combination with a H2-antihistamine
            E. A second generation H1-antihistamine in combination with a first-generation H1-antihistamine at bedtime
         iii. A second generation H1-antihistamine in combination with hydroxyzine or doxepin
      IV. Prescriber is, or has consulted with, an Allergist or Immunologist
3. **Add-on maintenance treatment for Nasal Polyps:**
   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 nasal polyps 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

B. **Nucala** may be approved for patient 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:
  - A. A long-acting beta agonist [if not already using a ICS-LABA combination]
  - B. An asthma-indicated long-acting anticholinergic agent
  - C. A leukotriene modifier
  - D. 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-alpha 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

C. **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:
          A. A long-acting beta agonist [if not already using a ICS-LABA combination]
          B. An asthma-indicated long-acting anticholinergic agent
          C. A leukotriene modifier
          D. 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 may be granted for 6 months of therapy
B. 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:
  1. Reduction in asthma symptoms (wheezing, coughing, shortness of breath, chest tightness)
  2. Reduction in administration frequency of short-acting rescue medication

3. Reduction in exacerbation frequency and asthma-related hospitalizations (no increase in inhaled or oral corticosteroid dose)
4. Elevation in predicted FEV1 from the patient's baseline before treatment.

C. Continuation of CSU therapy: Approval may be extended in 12-month intervals with documentation showing the patient's clinical improvement as evidenced by a decrease in severity of itching, or size/number of hives.

D. 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:
1. Decrease in maintenance dose of systemic corticosteroids
2. Improvement in BVAS score compared to baseline
3. Improvement in asthma symptoms or exacerbations
4. 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
5. Improvement in duration of remission, or decrease in the rate of relapses

E. Continuation of Nasal Polyps treatment: 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

F. 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:
1. Reduction in frequency of HES flares
2. Maintenance or reduction in background HES therapy usage

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

IV. EXCLUSIONS

A. Xolair, Nucala, and Fasenra will not be approved for uses and indications that are not FDA-approved or guideline-supported.

B. Xolar, Nucala, and Fasenra will not be covered for concurrent use with another biologic product.

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. CODES

Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.

Medication	HCPCS/CPT Code
Xolair 150 MG/ML SOSY Injection, omalizumab, 5 mg	J2357
Nucala 100 MG SOLR Injection, mepolizumab, 1 mg	J2182
Fasenra 30 MG/ML SOSY Injection, benralizumab, 1 mg	J0517

VII. REFERENCES

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VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
7/02/2014	Addition of CIU
4/20/2016	Addition of criteria for Nucala; Updated Xolair criteria, Expanded reauthorization criteria

6/13/2016	Clarification of policy criteria for Xolair and Nucala
7/15/2016	Updated the age restriction for Xolair's moderate to severe persistent asthma indication based on the FDA's updated approval PI
1/9/2017	Clarification of the previous maintenance controller criteria for both Xolair and Nucala
7/27/2017	Updated Exclusions section regarding physician samples
4/18/2018	Added clinical criteria for Nucala's EGPA indication; added clinical criteria for Fasenra
07/01/2018	Removed EHP Line of Business
12/19/2018	Updated layout and removed Fasenra as an applicable drug
01/16/2019	Added Fasenra back to the policy with its specific J-code
11/26/2019	Clarified Nucala criteria based on new FDA-approval for asthma in pediatric patients 6 years and older
01/15/2020	No policy changes- presented policy for USFHP adoption effective 3/1/2020
01/16/2020	Clarified exclusion criteria regarding concurrent biologic usage
05/13/2021	Updated authorization guidance
11/09/2021	Removed Priority Partners as an applicable LOB
01/18/2023	Updated criteria layout; Added criteria for Xolair and Nucala per FDA-labeling

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