HIGHMARK HEALTH OPTIONS

Updated: 06/2022
DMMA Approved: 07/2022

Request for Prior Authorization for Asthma & Allergy Biologics
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Allergy & Asthma Biologics require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Allergy & Asthma Biologics Prior Authorization Criteria:

Asthma and Allergy Biologics includes Adbry (tralokinumab), Cinqair (reslizumab), Dupixent (dupilumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab), and Xolair (omalizumab). New products with this classification will require the same documentation.

For all requests for Asthma and Allergy Biologics, all of the following criteria must be met in addition to the diagnosis specific criteria below:

- Must be prescribed by, or in consultation with, an allergist, dermatologist, ear/nose/throat specialist, gastroenterologist, immunologist, pulmonologist, or rheumatologist
- Is prescribed for an FDA-approved or medically accepted indication
- Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- For non-preferred agents, the member has had a trial and failure of a preferred agent or submitted a clinical reason for not having a trial of a preferred agent

Coverage may be provided with a diagnosis of **asthma** and the following criteria is met:

- Has an asthma severity that is consistent with the FDA-approved indication for the prescribed product
- The member meets the following drug-specific requirements:
    - For Cinqair (reslizumab):
        - Eosinophil count ≥ 400 cells/µL within 4 weeks of treatment initiation
    - For Dupixent:
        - Eosinophil count ≥ 150 cells/µL within 4 weeks of treatment initiation; **OR**
        - Is dependent on oral corticosteroids
    - For Fasenra (benralizumab):
        - Eosinophil count ≥ 150 cells/µL within 4 weeks of treatment initiation
    - For Nucala (mepolizumab):
        - Eosinophil count ≥ 150 cells/µL within 6 weeks of treatment initiation; **OR**
        - Eosinophil count ≥ 300 cells/µL in the past 12 months
    - For Tezspire (tezepelumab), both of the following:
        - Pre-bronchodilator FEV1 < 80% for adults OR < 90% for adolescents
        - Required systemic (oral or parenteral) corticosteroids ≥ 2 times in the past year **OR** required hospitalization for asthma exacerbation in the past year
    - For Xolair (omalizumab), all of the following:
        - Baseline FEV1 < 80%
        - Positive skin test or in vitro reactivity to a perennial aeroallergen

        - Must have one of the following:
            - Required systemic (oral or parenteral) corticosteroids to control asthma exacerbations ≥ 2 times in the past year
            - Required hospitalization due to an asthma exacerbation within the past year
            - Exacerbations return when the dose of inhaled/and or systemic corticosteroids are lowered
- Symptoms have been uncontrolled despite adherence with at least a three month trial of controller medications consisting of BOTH of the following:
    - An inhaled corticosteroid
    - Another asthma controller medication (e.g. long-acting beta agonist, leukotriene receptor antagonist, theophylline)
- The requested medication will be used in conjunction with ONE of the following:
    - A combination inhaled corticosteroid/long-acting-beta-agonist product
    - Combination therapy consisting of BOTH of the following:
        - An inhaled corticosteroid
        - An additional standard asthma controller medication (e.g., long-acting beta agonist, leukotriene receptor antagonist, etc.)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation the member had a positive clinical response or stabilization as demonstrated by one of the following:
        - An increase in the member's FEV_1
        - A decreased need for systemic corticosteroids
        - A decrease in the number of asthma related hospitalizations
        - A reduction in reported asthma-related symptoms
    - Adjunctive therapies (inhaled corticosteroids, long-acting beta-2 agonist, leukotriene receptor antagonist, theophylline) must be consistently filled per pharmacy claims history
        - If pharmacy claims do not confirm fills within the previous 2 months, the request will be denied
- **Reauthorization Duration of approval:**12 months

Coverage may be provided with a <u>diagnosis</u> of **Moderate to Severe Atopic dermatitis** and the following criteria is met:

- In addition to pruritic skin, member must have at least three of the following:
    - History of skin creases being involved. These include: antecubital fossae, popliteal fossae, neck, areas around eyes, fronts of ankles.
    - History of asthma or hay fever
    - The presence of generally dry skin within the past year.
    - Symptoms beginning before the age of two years.
    - Visible dermatitis involving flexural surfaces.
- Documentation showing the member has tried and failed TWO of the following or had an intolerance or contraindication to all of the following:

  - Medium to high potency topical corticosteroid
  - Topical calcineurin inhibitor [Protopic (tacrolimus)* or Elidel (pimecrolimus)*]
  - Systemic immunosuppressive therapy (e.g., cyclosporine, azathioprine, methotrexate)
  - Phototherapy
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Member has experienced improvement
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **eosinophilic granulomatosis with polyangiitis (EGPA)** and the following criteria is met:

- Documentation of at least four of the following diagnostic criteria:
  - Asthma
  - Eosinophilia (>10% eosinophils on the differential leukocyte count)
  - Mononeuropathy or polyneuropathy
  - Migratory or transient pulmonary infiltrates on chest x-rays
  - Paranasal sinus abnormalities
  - Biopsy containing a blood vessel with extravascular eosinophils
- The member has been stable on corticosteroids for at least 4 weeks or the prescriber has indicated clinical inappropriateness of corticosteroid therapy
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Must provide documentation of disease remission
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of **hypereosinophilic syndrome (HES)** and the following criteria is met:

- Must provide documentation that member is not FIP1L1-PDGFRα kinase-positive
- Provider attests that member does not have non-hematologic secondary HES (e.g. drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy)
- Must provide documentation of at least 2 HES flares (worsening of clinical signs and symptoms of HES or increasing eosinophils on at least 2 occasions) within the past 12 months and a blood eosinophil count ≥ 1,000 cells/mcL during screening
- Must provide documentation of trial and failure, contraindication, or intolerance to corticosteroids in addition to a trial of hydroxyurea or an interferon alpha product.
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
  - Must provide documentation of decrease in HES flares defined as HES-related worsening of clinical symptoms or blood eosinophil counts requiring an escalation in therapy
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of chronic rhinosinusitis with **nasal polyps** (CRSwNP), provided the following criteria is met:

- Medication must be used for add-on maintenance therapy
- Must provide documentation showing the member has tried and failed (which will be verified via pharmacy claims if available) or had an intolerance or contraindication to ALL of the following:
    - Intranasal or oral corticosteroid
    - Nasal saline irrigations
    - Antibiotics (if suspected concomitant infection)
- Member has relapsed from sinus surgery or has a contraindication to sinus surgery
- Member must have documentation of at least two of the following symptoms:
    - Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
    - Facial pain/pressure
    - Reduction or loss of smell
- **Initial Duration of Approval:** 12 months
- **Reauthorization criteria**
    - Must provide documentation of improvement in any of the following symptoms:
        - Nasal blockade/obstruction/congestion or nasal discharge (anterior/posterior nasal drip)
        - Facial pain/pressure
        - Reduction or loss of smell
- **Reauthorization Duration of approval:** 12 months

Coverage may be provided with a diagnosis of **chronic idiopathic urticaria** and the following criteria is met and the following criteria is met:

- Must have a documented history of urticaria for a period of at least 3 months
- Must have documented therapeutic failure despite adherence with a four-week trial, or contraindication or intolerance to, **BOTH** of the following:
    - A second-generation H1 antihistamine at the maximum tolerated dose
    - A second-generation H1 antihistamine in combination with one of the following
        - Leukotriene receptor antagonist (LTRA)
        - H2 antihistamine
        - First-generation H1 antihistamine
        - Another second-generation H1 antihistamine
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Documentation that demonstrates the member is tolerating and responding (e.g., documented improvement in condition)
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided with a diagnosis of **eosinophilic esophagitis** and the following criteria is met:

- Must have symptoms of dysphagia
- Must have documentation of ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) following a treatment course of proton pump inhibitor (PPI)
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
  - Must provide documentation of improvement
- **Reauthorization Duration of approval:** 12 months

* May require prior authorization

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

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ASTHMA & ALLERGY BIOLOGICS
PRIOR AUTHORIZATION FORM – PAGE 1 of 3

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Diagnosis:	ICD Code:

ASTHMA

What is the severity? ☐ Mild ☐ Moderate ☐ Severe

Is the member dependent on oral corticosteroids? ☐ Yes ☐ No

For Nucala, Cinqair, Dupixent, Fasenra: Eosinophil count: ☐ 0-149 ☐ 150-299 ☐ 300-399 ☐ ≥ 400 Date of test: _____

For Tezspire and Xolair:

- FEV1: ☐ < 80% ☐ 80-89% ☐ ≥ 90%
- How many times in the past year have systemic corticosteroids been required? ☐ None ☐ 1 ☐ ≥ 2
- Have they been hospitalized for an asthma exacerbation in the past year? ☐ Yes ☐ No
- Do exacerbations return when the dose of inhaled and/or systemic corticosteroids are lowered? ☐ Yes ☐ No

What will this medication be used with? Please check all that apply.

- ☐ Combination inhaled corticosteroid/long-acting-beta-agonist
- ☐ Inhaled corticosteroid
- ☐ Standard asthma controller medication (e.g. long-acting beta agonist, leukotriene receptor agonist)

MODERATE – SEVERE ATOPIC DERMATITIS

Which of the following apply to the member? Please check all that apply.

- ☐ Pruritic skin
- ☐ Involvement of skin creases
- ☐ History of asthma or hay fever
- ☐ Generally dry skin within the past year
- ☐ Symptoms beginning before age 2
- ☐ Visible dermatitis involving flexural surfaces

What has been tried? (Please list below)

- ☐ Topical corticosteroid
- ☐ Protopic (tacrolimus) or Elidel (pimecrolimus)
- ☐ Phototherapy
- ☐ Systemic immunosuppressive (e.g. cyclosporine, azathioprine, methotrexate)

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PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 3

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

CHRONIC IDIOPATHIC URTICARIA (CIA)
How long has the urticaria been present? ☐ < 3 months ☐ ≥ 3 months
What has been tried? Check all that apply.
- ☐ Second-generation H1 antihistamine at the maximum tolerated dose
- ☐ Second generation H1 antihistamine + Leukotriene receptor antagonist (LTRA)
- ☐ Second generation H1 antihistamine + H2 antihistamine
- ☐ Second generation H1 antihistamine + First-generation H1 antihistamine
- ☐ 2 second generation H1 antihistamines together

CHRONIC RHINOSINUSITIS WITH NASAL POLYPS (CRSwNP)
Is this being used as add-on maintenance therapy? ☐ Yes ☐ No
Has the member had sinus surgery? ☐ Yes ☐ No (please provide rationale for therapy below)
What symptoms are present? Check all that apply:
- ☐ Nasal blockage/obstruction/congestion or nasal discharge
- ☐ Facial pain or pressure
- ☐ Reduction of loss or smell

What has been tried?
- ☐ Intranasal or oral corticosteroid
- ☐ Nasal saline irrigation

Is infection suspected? ☐ Yes ☐ No
If yes, have antibiotics been tried? ☐ Yes ☐ No

EOSINOPHILIC GRANULOMATOSIS with POLYANGIITIS (EGPA)
Which of the following are present? Check all that apply.
- ☐ Asthma
- ☐ Eosinophilia (>10%)
- ☐ Paranasal sinus abnormalities
- ☐ Migratory or transient pulmonary infiltrates on chest x-rays
- ☐ Mononeuropathy or polyneuropathy
- ☐ Biopsy containing a blood vessel with extravascular eosinophils

Have corticosteroids been tried? ☐ Yes ☐ No (please provide reason below)

EOSINOPHILIC ESOPHAGITIS
Does the member have dysphagia? ☐ Yes ☐ No
What is the intraepithelial eosinophils per high-power field (eos/hpf) after treating with a PPI? ☐ < 15 eos/hpf ☐ ≥ 15 eos/hpf

HYPEREOSINOPHILIC SYNDROME (HES)
Is it FIP1L1-PDGFRαkinase-positive? ☐ Yes ☐ No
Has non-hematologic secondary HES been ruled out? ☐ Yes ☐ No
What is the blood eosinophil count? ☐ < 1,000 cells/mcL ☐ ≥ 1,000 cells/mcL
How many HES flares have occurred in the past year? ☐ < 2 ☐ ≥ 2
What has been tried? Check all that apply and list below.
- ☐ Corticosteroids
- ☐ Hydroxyurea
- ☐ Interferon alpha product

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ASTHMA & ALLERGY BIOLOGICS
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 3 OF 3

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MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Weight:	Height:

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced improvement with treatment? ☐ Yes ☐ No

ASTHMA

Which of the following has been experienced since starting treatment? Check all that apply.

- ☐ Increase in FEV1
- ☐ Decreased need for systemic corticosteroids
- ☐ Decrease in asthma related hospitalizations
- ☐ Reduction in asthma-related symptoms

What is this medication currently being used with? Please check all that apply.

- ☐ Combination inhaled corticosteroid/long-acting-beta-agonist
- ☐ Inhaled corticosteroid
- ☐ Standard asthma controller medication (e.g. long-acting beta agonist, leukotriene receptor agonist)

NASAL POLYPS

Please indicate what has improved as a result of therapy:

- ☐ Nasal blockade/obstruction/congestion or nasal discharge
- ☐ Facial pain or pressure
- ☐ Reduction of loss or smell

FOR EGPA, is disease in remission? ☐ Yes ☐ No

FOR HES, what has been experienced as a result of therapy?

- ☐ Decrease in HES flares
- ☐ Worsening of symptoms or blood eosinophil counts requiring an escalation in therapy

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date