

Initial approval will be granted for 6 months. Reauthorization will be granted for 12 months.

Future FDA-approved changes not currently listed on this form will be reviewed based upon the package insert information and any prerequisite treatment requirements for that indication.

Non-preferred products require a trial of preferred agents with the same indication or will only be considered with documentation of why the preferred product is not appropriate.

All of the following documentation is required for prior authorization review:

## I. Eosinophilic Asthma

### Initial Authorization

- Diagnosis of moderate to severe eosinophilic asthma for **Dupixent** in members  $\geq 6$  years old; **OR**
  - Diagnosis of severe eosinophilic asthma for **Fasenra** in members  $\geq 6$  years old; **OR**
  - Diagnosis of severe eosinophilic asthma for **Nucala** in members  $\geq 6$  years old
- AND**
- Eosinophil count  $\geq 150$  cells/ $\mu$ L within the past 6 weeks
- AND**
- At least one exacerbation (Oral corticosteroid burst, ER visit, hospitalization, or office visit) in the past 12 months while on and adherent\*\* to **one** of the following combination therapies:
    - A medium-high dose or max-tolerated inhaled corticosteroid + controller therapy; **OR**
    - A medium-high dose or max-tolerated inhaled corticosteroid + long-acting beta-2 agonist;
- AND**
- Will continue use of combination therapy with prescribed add-on maintenance drug
- AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker
- AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

### Reauthorization

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - Decreased frequency of exacerbations
  - Increase in percent predicted FEV<sub>1</sub> from pre-treatment baseline
  - Decreased use of rescue medication

- Decrease in severity of frequency of asthmatic symptoms (wheezing, shortness of breath, coughing)

**AND**

- Continued use of combination therapy with prescribed add-on maintenance drug

**AND**

- Compliance\*\* with therapy confirmed by refill history

**\*\*Adherence and compliance defined as:** evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months)

## II. Oral Corticosteroid-Dependent Asthma

### Initial Authorization

- Diagnosis of oral corticosteroid-dependent asthma for **Dupixent** in members  $\geq 6$  years old [at least two oral steroid courses in the past 12 months]

**AND**

- Uncontrolled asthma symptoms in the past 12 months while on and adherent\*\* to **one** of the following:
  - A medium-high or max-tolerated inhaled corticosteroid + controller therapy; **OR**
  - A medium-high or max-tolerated inhaled corticosteroid + long-acting beta-2 agonist;

**AND**

- Will continue use of combination therapy with prescribed add-on maintenance drug

**AND**

- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker

**AND**

- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

### Reauthorization

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - Decreased frequency of exacerbations
  - Increase in percent predicted FEV<sub>1</sub> from pre-treatment baseline
  - Decreased use of rescue medication
  - Decrease in severity of frequency of asthmatic symptoms (wheezing, shortness of breath, coughing)

**AND**

- Continued use of combination therapy with prescribed add-on maintenance drug

**AND**

- Compliance\*\* with therapy confirmed by refill history

**\*\*Adherence and compliance defined as:** evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months)

### III. Allergic Asthma

#### Initial Authorization

- Diagnosis of moderate to severe persistent asthma for **Xolair** in members  $\geq 6$  years of age  
**AND**
- A positive test result to a perennial aeroallergen  
**AND**
- Submission of current lab work for serum IgE levels measured before the start of treatment  
**AND**
- At least one exacerbation (Oral corticosteroid burst, ER visit, hospitalization, or office visit) in the past 12 months while on and adherent\*\* to **one** of the following:
  - A medium-high or max-tolerated inhaled corticosteroid + controller therapy; **OR**
  - A medium-high or max-tolerated inhaled corticosteroid + long-acting beta-2 agonist;**AND**
- Will continue use of combination therapy with prescribed add-on maintenance drug  
**AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker  
**AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

#### Reauthorization

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - Decreased frequency of exacerbations
  - Increase in percent predicted FEV<sub>1</sub> from pre-treatment baseline
  - Decreased use of rescue medication
  - Decrease in severity of frequency of asthmatic symptoms (wheezing, shortness of breath, coughing)**AND**
- Continued use of combination therapy with prescribed drug  
**AND**
- Compliance\*\* with therapy confirmed by refill history

**\*\*Adherence and compliance defined as:** evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months)

### IV. Severe Persistent Asthma

#### Initial Authorization

- Diagnosis of severe persistent asthma for **Tezspire** in members  $\geq 12$  years of age

**AND**

- At least one exacerbation (Oral corticosteroid burst, ER visit, hospitalization, or office visit) in the past 12 months while on and adherent\*\* to **one** of the following:
  - A medium-high dose or max-tolerated inhaled corticosteroid + controller therapy; **OR**
  - A medium-high dose or max-tolerated inhaled corticosteroid + long-acting beta-2 agonist;

**AND**

- Will continue use of combination therapy with prescribed add-on maintenance drug

**AND**

- Will not be used in combination with any interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker

**AND**

- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

**Reauthorization**

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - Decreased frequency of exacerbations
  - Increase in percent predicted FEV<sub>1</sub> from pre-treatment baseline
  - Decreased use of rescue medication
  - Decrease in severity of frequency of asthmatic symptoms (wheezing, shortness of breath, coughing)

**AND**

- Continued use of combination therapy with prescribed add-on maintenance drug

**AND**

- Compliance\*\* with therapy confirmed by refill history

**\*\*Adherence and compliance defined as:** evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months)

## **V. Moderate to Severe Atopic Dermatitis**

**Initial Authorization**

- Diagnosis of moderate to severe atopic dermatitis for Dupixent in members ≥ 6 months of age; **OR**
- Diagnosis of moderate to severe atopic dermatitis for Adbry in members ≥ 12 years of age; **OR**
- Diagnosis of moderate to severe atopic dermatitis for Ebglyss in members ≥ 12 years of age and weighing ≥ 40 kg; **OR**
- Diagnosis of moderate to severe atopic dermatitis for Nemluvio in members ≥ 12 years of age

**AND**

- Inadequate response or intolerance to a ≥ 14-day trial of a medium to high potency topical corticosteroid

**AND**

- Inadequate response or intolerance to a 6-week trial of a topical calcineurin inhibitor

**AND**

- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker

### Reauthorization

- A positive clinical response to therapy as confirmed by a decrease in severity of atopic dermatitis symptoms (skin inflammation and pruritus)

#### AND

- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## VI. Eosinophilic Granulomatosis with Polyangiitis (EGPA)

### Initial Authorization

- Diagnosis of eosinophilic granulomatosis with polyangiitis for Fasenra in adults; **OR**
- Diagnosis of eosinophilic granulomatosis with polyangiitis for Nucala in adults

#### AND

- Disease is relapsing or refractory with **two** of the following:
  - History or presence of asthma; **AND/OR**
  - Eosinophilia (> 10% of total WBCs); **AND/OR**
  - Evidence of 2 or more features of EGPA (histopathological evidence, non-fixed pulmonary infiltrates, cardiomyopathy, alveolar hemorrhage, etc.)

#### AND

- Currently on a stable dose of oral prednisone or prednisolone for ≥ 4 weeks

#### AND

- Must submit baseline blood eosinophil count dated within the past 6 weeks

#### AND

- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker

#### AND

- Prescribed by or in consultation with an allergist, immunologist, pulmonologist or rheumatologist

### Reauthorization

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - Reduction in relapses
  - Reduction in glucocorticoid dose

#### AND

- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## VII. Hypereosinophilic Syndrome (HES)

### Initial Authorization

- Diagnosis of HES for  $\geq 6$  months for **Nucala** in members  $\geq 12$  years old  
**AND**
- No identifiable non-hematologic secondary cause  
**AND**
- Two or more HES flares within the past 12 months as evidenced by at least **one** of the following:
  - Worsening of clinical signs/symptoms
  - Increased eosinophils on  $\geq 2$  occasions
  - An increase/addition of oral corticosteroids or cytotoxic or immunosuppressive therapy**AND**
- Blood eosinophil count  $\geq 1000$  cells/ $\mu$ L  
**AND**
- Must submit baseline blood eosinophil count dated within the past 6 weeks  
**AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker  
**AND**
- Prescribed by or in consultation with an allergist, cardiologist, hematologist, immunologist, oncologist, or pulmonologist

### Reauthorization

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - A reduction in the number of flares
  - Decreased blood eosinophil count from baseline**AND**
- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## VIII. Chronic Spontaneous Urticaria (CSU)

### Initial Authorization

- Diagnosis of CSU for at least 3 months for **Dupixent** in members  $\geq 12$  years of age; **OR**
- Diagnosis of CSU for at least 3 months for **Xolair** in members  $\geq 12$  years of age  
**AND**
- Inadequate response or contraindication to a 4-week trial of a second-generation H1 antihistamine  
**AND**

- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker

**AND**

- Prescribed by or in consultation with an allergist, dermatologist, or immunologist

### **Reauthorization**

- A positive clinical response to therapy as confirmed by a decrease in severity of CSU symptoms (hives/wheals, pruritus, angioedema)

**AND**

- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## **IX. Eosinophilic Esophagitis (EoE)**

### **Initial Authorization**

- Diagnosis of eosinophilic esophagitis for **Dupixent** in members  $\geq 1$  year of age and weighing  $\geq 15$  kg

**AND**

- Eosinophil count  $\geq 15$  eosinophils/high-power field

**AND**

- Inadequate response, contraindication, or technique difficulty to a swallowed topical corticosteroid; **OR**
- Inadequate response to a proton pump inhibitor

**AND**

- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker

**AND**

- Prescribed by or in consultation with an allergist, gastroenterologist, or immunologist

### **Reauthorization**

- A positive clinical response to therapy as confirmed by a decrease in inflammation and/or dysphagia

**AND**

- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## **X. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**

### **Initial Authorization**

- Diagnosis of CRSwNP by evidence of the presence of bilateral nasal polyps for **Dupixent** in members  $\geq 12$  years of age; **OR**
- Diagnosis of CRSwNP by evidence of the presence of bilateral nasal polyps for **Nucala** in adults; **OR**

- Diagnosis of CRSwNP by evidence of the presence of bilateral nasal polyps for **Tezspire** in members  $\geq 12$  years of age; **OR**
- Diagnosis of CRSwNP by evidence of the presence of bilateral nasal polyps for **Xolair** in adults  
**AND**
- Presence of bilateral nasal polyps confirmed by at least one of the following:
  - Physical examination
  - Rhinoscopy
  - Nasal endoscopy
  - Diagnostic testing**AND**
- Inadequate response or contraindication to a  $\geq 8$ -week trial of an intranasal corticosteroid; **OR**
- Inadequate response or contraindication to a  $\geq 8$ -week trial of a systemic corticosteroid; **OR**
- Previous history of nasal polyp surgery  
**AND**
- For **Xolair**, must submit current lab work for serum IgE levels measured before the start of treatment  
**AND**
- Will use as add-on maintenance with an intranasal corticosteroid  
**AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker  
**AND**
- Prescribed by or in consultation with an allergist, immunologist, otolaryngologist, or pulmonologist

### Reauthorization

- A positive response to therapy as confirmed by a decrease in severity of symptoms (reduced inflammation or polyp size)  
**AND**
- Continued use with an intranasal corticosteroid  
**AND**
- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## XI. Prurigo Nodularis

### Initial Authorization

- Diagnosis of prurigo nodularis for **Dupixent** in adults; **OR**
- Diagnosis of prurigo nodularis for **Nemluvio** in adults  
**AND**
- Presence of  $\geq 20$  nodular lesions  
**AND**

- Inadequate response or contraindication to a medium or very high potency topical corticosteroid  
**AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker  
**AND**
- Prescribed by or in consultation with an allergist, dermatologist, or immunologist

### Reauthorization

- A positive clinical response to therapy as confirmed by **one** of the following:
  - A decrease in itch intensity
  - A decrease in the number of nodules**AND**
- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## XII. IgE-Mediated Food Allergy

### Initial Authorization

- Diagnosis of IgE-mediated (Type 1) food allergy for **Xolair** in members  $\geq 1$  year of age  
**AND**
- **One** of the following:
  - Positive serum test for IgE
  - Positive skin prick test
  - Positive response to allergenic food by oral food challenge**AND**
- Provide any history of IgE-mediated allergic reactions to peanuts, milk products, eggs, seafood, or any other food type  
**AND**
- Submission of current lab work for serum IgE levels measured before the start of treatment  
**AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker  
**AND**
- Prescribed by or in consultation with an allergist or immunologist

### Reauthorization

- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

### **XIII. Chronic Obstructive Pulmonary Disease (COPD) and an Eosinophilic Type**

#### **Initial Authorization**

- Diagnosis of COPD that is an eosinophilic phenotype for **Dupixent** in adults; **OR**
  - Diagnosis of COPD that is an eosinophilic phenotype for **Nucala** in adults
- AND**
- **One** of the following:
    - At least two moderate exacerbations (use of a systemic glucocorticoid, an antibiotic agent, ER visit, or office visit) in the past 12 months while on and adherent\*\* to **one** of the following:
      - A ≥ 90-day triple therapy [a long-acting muscarinic agent (LAMA) plus a long-acting Beta agonist (LABA) plus an inhaled corticosteroid (ICS)]; **OR**
      - A ≥ 90-day double therapy if ICS is contraindicated [LAMA + LABA]; **OR**
    - At least one exacerbation that led to hospitalization while on and adherent\*\* to a ≥ 90-day triple therapy
- AND**
- Will continue use of triple therapy (double therapy if ICS is contraindicated) with prescribed add-on maintenance drug
- AND**
- Baseline blood eosinophil (EOS) levels ≥ 300 cells  $\mu$ L
- AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker
- AND**
- Prescribed by or in consultation with an allergist, immunologist, or pulmonologist

#### **Reauthorization**

- A positive clinical response to therapy as confirmed by at least **one** of the following:
    - A decrease in the frequency of exacerbations
    - Dyspnea improvement
- AND**
- Continued use of triple therapy (double therapy if ICS is contraindicated) with prescribed add-on maintenance drug
- AND**
- Compliance\*\* with therapy confirmed by refill history

**\*\*Adherence and compliance defined as:** evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

## XIV. Bullous Pemphigoid (BP)

### Initial Authorization

- Diagnosis of bullous pemphigoid for **Dupixent** in adults  
**AND**
- Presence of  $\geq 3$  bullae lesions  
**AND**
- Inadequate response to a  $\geq 30$ -day trial of a topical or systemic corticosteroid therapy  
**AND**
- Will not be used in combination with any other interleukin IL-4, IL-5, IL-13, IL-31 antagonists or anti-immunoglobulin E (IgE) antibody, or thymic stromal lymphopoietin (TSLP) blocker  
**AND**
- Prescribed by or in consultation with an allergist, dermatologist, or immunologist

### Reauthorization

- A positive clinical response to therapy as confirmed by at least **one** of the following:
  - A decrease in itch intensity
  - A decrease in the number of bullae lesions**AND**
- Compliance with therapy confirmed by refill history as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months