PHARMACY COVERAGE GUIDELINE

DUPIXENT® (dupilumab) injection
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

➢ **Criteria for initial therapy:** Dupixent (dupilumab) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Allergist, Immunologist, Pulmonologist, Otolaryngologist, Gastroenterologist, or Dermatologist depending upon indication or use

2. Individual has a confirmed diagnosis of **ONE** of the following:
    a. Individual is 6 years of age or older with **moderate-to-severe asthma** characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma, used as add-on maintenance treatment

b. Individual 6 months of age or older with **moderate-to-severe atopic dermatitis (AD)** that is not adequately controlled with topical prescription therapies or when those therapies are not advisable

c. Individual 12 years of age or older with inadequately controlled **chronic rhinosinusitis with nasal polyposis (CRSwNP)**, used as add-on maintenance treatment

d. Individual is 1 years of age or older weighing at least 15 kg, with **eosinophilic esophagitis (EoE)**

e. Individual is 18 years of age or older with **prurigo nodularis (PN)**

f. Individual is 18 years of age or older with inadequately controlled **chronic obstructive pulmonary disease (COPD)** and an eosinophilic phenotype, used as add-on maintenance treatment

g. Individual 12 years of age or older who weighs at least 66 pounds (30 Kg) with **chronic spontaneous urticaria (CSU)** who continues to have symptoms that are not controlled with H1 antihistamine treatment

3. **ONE** of the following:
   a. **For uncontrolled moderate to severe asthma**:
      i. Individual's asthma pre-treatment was described as at least persistent and moderate to severe in severity (see Definitions section)
      ii. Individual has **ONE** of the following types of asthma:
         1. Eosinophilic asthma with blood eosinophils greater than or equal to 150 cells/microliter within the last 6-weeks or has a history of blood eosinophils greater than or equal to 300 cells/microliter
         2. Corticosteroid dependent asthma requiring a minimum oral daily dose of prednisone 5 mg (or an equivalent dose of another corticosteroid)
      iii Dupixent will be used as add-on maintenance therapy (i.e., will continue inhaled corticosteroid)
      iv. Asthma is uncontrolled, defined by **ONE** of the following:
         1. Asthma Control Test (ACT) score is currently less than 20
         2. Has experienced two or more asthma exacerbations requiring treatment with systemic corticosteroids in the previous year
         3. Has experienced one or more severe asthma exacerbations requiring hospitalization, or emergency room visits in the previous year
         4. Has a FEV1 less than 80% predicted
         5. Requires oral corticosteroid maintenance therapy
   b. **For moderate to severe atopic dermatitis (AD):**
      i. Lesions involve at least 10% of body surface area or involve sensitive areas of the face, head, neck, hands, feet, groin, or intertriginous areas
      ii. Current weekly averaged worst daily peak pruritus Numeric Rating Scale (NRS) of at least 3
      iii. **ONE** of the following disease intensity measures:
         1. Disease severity defined by an Investigator's Global Assessment (IGA) score at least 3 in the overall assessment of lesions
         2. Eczema Area and Severity Index (EASI) score of at least 7

c. **For chronic rhinosinusitis with nasal polyps (CRSwNP):**
   i. Evidence of nasal polyposis by direct examination, endoscopy, or sinus CT scan
   ii. Individual has 12 weeks or more of anterior or posterior rhinorrhea and **TWO** of the following:
      1. Mucopurulent discharge
      2. Nasal obstruction/congestion
      3. Facial pain/pressure
      4. Diminished or loss of sense of smell
   iii. Dupixent will be used as add-on maintenance therapy with intranasal corticosteroids

d. **For eosinophilic esophagitis (EoE) ALL of the following:**
   i. Individual weighs at least 15 kilograms
   ii. Individual has symptoms of dysphagia with solid foods
   iii. Endoscopic biopsy results demonstrate 15 or greater intraepithelial eosinophils per high power field (eos/hpf) [must submit copy of endoscopy report]

e. **For prurigo nodularis (PN):**
   i. Individual has a Worst Itch-Pruritus Numeric Rating Scale of 7 or more (see Definitions section)
   ii. Individual has at least 20 or more nodular/pruriginous lesions on both legs, and/or both arms and/or trunk which correspond to an IGA stage of 3 or more (see Definitions section)

f. **For moderate-to-severe chronic obstructive pulmonary disease (COPD):**
   i. Individual has moderate-to-severe signs and symptoms of chronic bronchitis (chronic productive cough, dyspnea, wheezing, increased sputum volume and/or increased sputum purulence) in the absence of other known causes of chronic cough
   ii. Individual has a Medical Research Council Dyspnea Scale (MRC) of at least grade 2 (see Definitions section)
   iii. Individual has post-bronchodilator FEV1/FVC <0.70 and post-bronchodilator ppFEV1 >30% and ≤70%
   iv. There is documentation of type 2 inflammation (ex., blood eosinophils ≥300 cells/µL)
   v. Individual has a documented history of high exacerbation risk defined as ≥2 moderate or ≥1 severe exacerbation within the previous year with at least 1 exacerbation occurring while taking ICS+LABA+LAMA, or LABA+LAMA if ICS is contraindicated
   vi. Moderate to severe exacerbations required systemic corticosteroids and/or antibiotics or required hospitalization or observation for over 24 hours in an emergency department or urgent care facility (see Definitions section)
   vii. Individual does not have **ANY** of the following:
      1. Significant pulmonary disease other than COPD (e.g., lung fibrosis, sarcoidosis, interstitial lung disease, etc.)
      2. Cor pulmonale, evidence of right heart failure
      3. Treatment with oxygen of more than 12 hours per day
      4. Hypercapnia requiring Bi-level ventilation
      5. Respiratory infection
      6. A diagnosis of alpha-1 anti-trypsin deficiency

g. **For chronic spontaneous urticaria (CSU):**
   i. Individual does not have other forms of urticaria or other skin diseases with chronic itching other than those associated with CSU
   ii. Individual has itch and hives on most days of the week for at least 6 consecutive weeks over the last 6 months

iii. Weekly urticaria activity score (UAS7) score is at least 16
iv. Weekly itch severity score (ISS7) score is at least 8

4. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
   a. **For moderate-to-severe asthma with uncontrolled symptoms:**
      i. At least a 3-month trial of a daily controller medication regimen including use of maximally dosed inhaled corticosteroid **AND** long-acting inhaled beta-agonist **OR** use of another asthma controlling medication regimen to prevent symptoms
      ii. Has access to a reliever medication such as an inhaled short-acting beta-agonist for rapid treatment of symptoms
   b. **For moderate-to-severe atopic dermatitis (AD)**:
      i. At least a 2 consecutive month trial of **ONE** of the following topical treatments:
         1. Medium to high potency corticosteroid
         2. Calcineurin inhibitor (Protopic (tacrolimus) or Elidel (pimecrolimus))
         3. Phosphodiesterase 4 inhibitor (Eucrisa (crisaborole))
   c. **For chronic rhinosinusitis with nasal polyposis (CRSwNP):**
      i. At least a 3-month trial of maximally tolerated intra-nasal corticosteroid
      ii. Nasal saline irrigation without or with short course of systemic corticosteroid for individuals with complete obstruction
      iii. Individual has previously undergone functional endoscopic sinus surgery (FESS) with recurrence of disease following surgery or is not a surgical candidate or has a comorbid condition where Dupixent (dupilumab) can control comorbid condition symptoms
   d. **For eosinophilic esophagitis (EoE):**
      i. At least a 2-month trial of a topical corticosteroid (e.g., budesonide, fluticasone) [**Note**: Relapse of symptoms after discontinuing therapy is not considered a failure]
   e. **For prurigo nodularis (PN) ONE** of the following:
      i. For limited number of nodular lesions there is a history of failing a 2-week course of very high potency topical corticosteroid (TCS) with or without intralesional corticosteroid injections or when TCS are not medically advisable (see Definitions section)
      ii. Widespread/recalcitrant disease with documented failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or not a candidate for phototherapy with narrowband ultraviolet B (NBUVB)
   f. **For moderate-to-severe chronic obstructive pulmonary disease (COPD):**
      i. Background therapy involves triple therapy with ICS+LABA+ LAMA, or double therapy with LABA+LAMA if ICS is contraindicated
      ii. Background therapy must be continued
   g. **For chronic spontaneous urticaria (CSU) TWO** of the following**:** (see Definitions section)
      i. At least a 2-week trial of non-sedating H1 antihistamine at four times the FDA-approved dose
      ii. At least a 2-week trial of non-sedating H1 antihistamine in combination with a H2 antihistamine
      iii. At least a 4-week trial of a leukotriene modifiers (e.g., montelukast, zafirlukast) in combination with an H1 antihistamine

5. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

6. There is no concurrent use with Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab), Xolair (omalizumab), Adbry (tralokinumab), Rinvoq (upadacitinib), Cibinqo (abrocitinib), or any other biologic therapy [e.g., rituximab (Rituxan and rituximab biosimilars), infliximab (Remicade and infliximab biosimilars), Enbrel (etanercept)]

7. Dupixent is not being used concurrently with live vaccines

Initial approval duration: 4 months

- **Criteria for continuation of coverage (renewal request):** Dupixent (dupilumab) and/or generic equivalent (if available) are considered ***medically necessary*** and will be approved when **ALL** the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Prescriber is a physician specializing in the patient's diagnosis or is in consultation with an Allergist, Immunologist, Pulmonologist, Otolaryngologist, Gastroenterologist, or Dermatologist depending upon indication or use

2. Individual's condition has responded while on therapy with response defined as the following:
    a. **For asthma**, achieved and maintains **TWO** of the following:
        i. Decreased incidence of asthma exacerbation
        ii. Decreased need for use of rescue medications
        iii. Decreased need for systemic corticosteroids
        iv. Decrease in hospitalizations/emergency room visits
        v. Improvement in FEV1 from baseline
        vi. Reduced severity or frequency of asthma related symptoms
    b. **For atopic dermatitis (AD)**, **ALL** of the following:
        i. No evidence of disease progression
        ii. Documented evidence of efficacy, disease stability and/or improvement
        iii. Achieved and maintains an IGA of 0 or 1 (clear or almost clear) **or** EASI-75 (improvement of at least 75%) in score from baseline
    c. **For chronic rhinosinusitis with nasal polyposis (CRSwNP)**, achieved and maintains **THREE** of the following:
        i. Reduction in sinus opacification
        ii. Reduction in nasal congestion
        iii. Reduction in rhinorrhea
        iv. Reduction in facial pain or pressure
        v. Improved sense of smell
        vi. Reduced need for systemic corticosteroid
        vii. No evidence of disease progression
    d. **For eosinophilic esophagitis (EoE)**, achieved and maintains **TWO** of the following:
        i. Significant reduction in dysphagia
        ii. Improvement in abdominal pain, reflux or heartburn, abdominal pain or vomiting

iii. Endoscopic biopsy results demonstrate less than 7 eosinophils per high power field (eos/hpf) or greater than 50% reduction from baseline

e. **For prurigo nodularis (PN)**, **BOTH** of the following:
   i. Improvement (reduction) in WI-Pruritus NRS by ≥ 4 points
   ii. Achieved and maintains 0-5 nodules/pruriginous lesions which corresponds to an IGA stage of 0 or 1

f. **For moderate-to-severe chronic obstructive pulmonary disease (COPD)**, **ANY** of the following**:**
   i. Reduced rate of moderate or severe exacerbations over baseline
   ii. Reduced number of moderate or severe exacerbations over baseline
   iii. Reduced use of systemic corticosteroids and/or antibiotics over baseline
   iv. Reduced hospitalizations or observations for over 24 hours in an emergency department or urgent care facility over baseline
   v. Improved post-bronchodilator FEV1 when added to background maintenance therapy

g. **For chronic spontaneous urticaria (CSU),** achieved and maintains **TWO** of the following:
   i. Decrease in severity of itching
   ii. Decrease in number of hives
   iii. Decrease in size of hives
   iv. Decrease in frequency urticaria episodes

3. **If available**: Individual has failure after adequate trial, contraindication per FDA label, intolerance, or is not a candidate for a **generic equivalent** [Note: Failure, contraindication or intolerance to the generic should be reported to the FDA] (see Definitions section)

4. Individual has been adherent with the medication and other medications for the condition being treated (topical agents for atopic dermatitis, inhaled corticosteroids for asthma, or intranasal corticosteroids for chronic rhinosinusitis)

5. Dupixent is not being used concurrently with live vaccines

6. There is no concurrent use with Cinqair (reslizumab), Fasenra (benralizumab), Nucala (mepolizumab), Tezspire (tezepelumab), Xolair (omalizumab), Adbry (tralokinumab), Rinvoq (upadacitinib), Cibinqo (abrocitinib), or any other biologic therapy for atopic dermatitis [e.g., rituximab (Rituxan and rituximab biosimilars), infliximab (Remicade and infliximab biosimilars), Enbrel (etanercept)]

7. Individual has not developed any significant adverse drug effects that may exclude continued use such as:
   a. Severe/serious systemic eosinophilia, eosinophilic pneumonia, or eosinophilic granulomatosis with polyangiitis
   b. Generalized urticaria, rash, erythema nodosum, erythema multiforme, and serum sickness or serum sickness-like reactions
   c. Persistent or worsening arthralgia or joint symptoms

Renewal duration: 12 months

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

PHARMACY COVERAGE GUIDELINE

DUPIXENT® (dupilumab) injection
Generic Equivalent (if available)

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Description:

Dupixent (dupilumab) is a monoclonal antibody, an interleukin-4 receptor alpha antagonist, is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe Atopic Dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. It can be used with or without topical corticosteroids. Dupixent (dupilumab) is indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe Asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma. It is **not** indicated for the relief of acute bronchospasm or status asthmaticus. Dupixent (dupilumab) is indicated as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled Chronic Rhinosinusitis with Nasal Polyps. Dupixent (dupilumab) is indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with Eosinophilic Esophagitis. Dupixent (dupilumab) is indicated for the treatment of adult patients with Prurigo Nodularis. Dupixent (dupilumab) is indicated as an add-on maintenance treatment of adult patients with inadequately controlled Chronic Obstructive Pulmonary Disease and an eosinophilic phenotype. It is **not** indicated for the relief of acute bronchospasm. Dupixent is indicated for the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment. Dupixent is not indicated for the treatment of other forms of urticaria.

Treatment of atopic dermatitis initially involves use of topical prescription therapies such as corticosteroids, calcineurin inhibitors (tacrolimus ointment, pimecrolimus cream) and topical phosphodiesterase 4 (PDE-4) inhibitors (crisaborole ointment). Topical corticosteroids are considered the standard of care; strength and formulation of the preparation is selected based on severity, duration of treatment, location of exacerbation, and age of individual. Topical calcineurin and topical PDE-4 inhibitors should be reserved for problem areas only, such as the face, neck, intertriginous and genital areas.

Asthma is a complex disorder characterized by variable and recurring clinical symptoms, airflow obstruction, bronchial hyper-responsiveness, and underlying inflammation.

Inflammation is an important component in the pathogenesis of asthma. Multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) are involved in inflammation.

Asthma can be divided into subtypes, which are associated with airway inflammation with eosinophils. It is estimated that about half of individuals with severe asthma exhibit the eosinophilic phenotype with elevated eosinophil levels (a marker of inflammation) in both the blood and airways. Activated eosinophils can increase airway smooth muscle contraction and mucous secretion. Interleukin-5 (IL-5) is an important cellular signal in eosinophilic inflammation.

About 10% of asthma patients have severe asthma that may be uncontrolled despite high doses of standard-of-care asthma controller medicines and can require the use of chronic oral corticosteroids (OCS). Severe,

uncontrolled asthma is debilitating and potentially fatal with patients experiencing frequent exacerbations and significant limitations on lung function and quality of life.

Inhaled corticosteroids are the most effective long-term therapy for control and management of asthma. Asthma is said to be well controlled when asthma symptoms are twice a week or less; rescue bronchodilator medication use is twice a week or less; there is no nocturnal or early morning awaking due to asthma symptoms; there are no limitations of work, school, or exercise; and the Forced Expiratory Volume (FEV1) is normal or the patient's personal best. On the other hand, indicators of asthma that is not adequately controlled include limitation of normal activities, poor lung function with FEV1 of < 80% predicted, at least 2 episodes per year of asthma exacerbations requiring oral systemic corticosteroids. More frequent and intense exacerbations requiring urgent, unscheduled care, hospitalization, or ICU admission point toward worse disease control.

Chronic rhinosinusitis (CRS) is an inflammatory condition of the nose and paranasal sinuses characterized by the presence of two or more of the following symptoms for greater than 12-weeks duration: 1) nasal blockage/obstruction/congestion; 2) nasal discharge that is mucopurulent; 3) facial pain/pressure; 4) reduction or loss of smell. Confirmation of the diagnosis is made by sinus CT scan or nasal endoscopy to determine if there is nasal polyposis in both nasal passages. In general, individuals with nasal polyposis (CRSwNP) have more extensive disease than CRS without nasal polyposis (CRSsNP). The underlying mechanisms that contribute to the chronic sinonasal inflammation observed in CRSwNP are not completely defined. Individuals with CRSwNP may also have concurrent diagnoses of asthma, chronic rhinitis, and allergic rhinitis.

Topical corticosteroids and nasal saline irrigations are recommended as initial therapy. Intranasal corticosteroids decrease nasal polyp size, lessen nasal symptoms, and improve patient quality of life. Oral corticosteroids can also reduce polyp size and improve symptoms but are associated with serious systemic side effects. Patients with significant sinonasal disease and/or those who fail medical management should be evaluated for sinus surgery. However, nasal polyps can reoccur despite sinus surgery.

Eosinophilic esophagitis (EoE) is a chronic, immune-mediated, esophageal disease characterized by symptoms related to esophageal dysfunction and histologically by eosinophil-predominant inflammation. Diagnostic criteria include symptoms related to esophageal dysfunction, esophageal biopsy, characteristically consisting of ≥15 eosinophils per high power field (HPF) (or 60 eosinophils per mm), and exclusion of other causes responsible for or contributing to symptoms and eosinophilia.

Established treatments for EoE include dietary therapy, proton pump inhibitors (PPIs) and topical corticosteroids. While PPIs and corticosteroids are not FDA approved treatment options, both are recognized as standard treatment per American College of Gastroenterology guidelines. Dupilumab is the first FDA approved treatment option for EoE.

Prurigo nodularis (PN) is an uncommon, chronic skin disorder affecting primarily older adults and is characterized by symmetrically distributed, multiple, firm, pruritic nodules. It occurs in patients with chronic severe pruritus and is frequently associated with a history of atopic dermatitis. PN is a distinctive reaction pattern that occurs from continuous scratching over a prolonged period of time. PN presents with firm, dome-shaped, itchy nodules that range in size from a few millimeters to several centimeters. They are often symmetrically distributed on the extensor surfaces of the arms and legs and on the trunk. The nodules can be flesh-colored, erythematous, or brown/black and range in number from few to hundreds. Pruritus is always severe and distressing. It can be paroxysmal, sporadic, or continuous and is worsened by heat, sweating, or irritation from clothing.

PHARMACY COVERAGE GUIDELINE

DUPIXENT® (dupilumab) injection
Generic Equivalent (if available)

Chronic spontaneous urticaria (CSU) is defined by the presence of recurrent urticaria, angioedema, or both for a period of six weeks or longer. CSU is self-limited, with an average duration of two to five years, but symptoms can significantly impact the quality of life. The urticarial lesions (also called hives or wheals) can vary in size and are usually surrounded by erythema. They are associated with an itching sensation that is usually limited to 30 minutes to 24 hours in duration. Disease severity is measured by a weekly urticaria activity score (UAS7, range 0–42), which is a composite of a weekly itch severity score (ISS7, range 0–21) and a weekly hive count score (HSS7, (range 0–21). The ISS7 score is the sum of the daily itch severity scores (ISS), from 0 to 3, recorded at the same time of the day for a 7-day period, ranging from 0 to 21. Dupixent showed significant improvement in ISS7 and UAS7 versus placebo for individuals who remained symptomatic despite H1 antihistamine and who were naive to anti-IgE treatment. Standard treatments include a second-generation H1 antihistamine which can be increased in dose or combined with other antihistamines or a leukotriene modifier. Short courses of steroids may be warranted but are usually avoided long-term. Individuals' refractory to H1 antihistamine regimens, may benefit from Dupixent (dupilumab) or Xolair (omalizumab).

Dupilumab is a human monoclonal IgG4 antibody that inhibits interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling by specifically binding to the interleukin-4 receptor alpha (IL-4Rα) subunit shared by the IL-4 and IL-13 receptor complexes. Dupilumab inhibits IL-4 signaling via the Type I receptor and both IL-4 and IL-13 signaling through the Type II receptor.

Inflammation is an important component in the pathogenesis of asthma, atopic dermatitis, chronic rhinosinusitis with nasal polyposis, and eosinophilic esophagitis. Multiple cell types that express IL-4Rα (mast cells, eosinophils, macrophages, lymphocytes, epithelial cells, goblet cells) and inflammatory mediators (histamine, eicosanoids, leukotrienes, cytokines, chemokines) are involved in inflammation. Blocking IL-4Rα with dupilumab inhibits IL-4 and IL-13 cytokine-induced inflammatory responses, including the release of pro-inflammatory cytokines, chemokines, nitric oxide, and IgE.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Adult: Age 18 years and older

Asthma:

Asthma *Severity* Classification:

	Classification of *Asthma Severity* (children 5 to 11 years of age)			
	Intermittent	Persistent		
		Mild	Moderate	Severe
Symptoms	≤ 2 days/week	> 2 days/week, but not daily	Daily	Throughout the day
Nighttime awakening	≤ 2 times/month	3 to 4 times/month	>1 time/week, but not nightly	Often 7times/week
SABA use for symptom control (not for prevention of EIB)	≤ 2 days/week	> 2 days/week, but not daily	Daily	Several times per day

Interference with normal activity	None	Minor limitation	Some limitation	Extremely limited
Lung function	Normal FEV1 between exacerbations	FEV1 is > 80% predicted	FEV1 is 60-80% predicted	FEV1 < 60% predicted
	FEV1 > 80% predicted	FEV1/FVC > 80%	FEV1/FVC is 75-80% predicted	FEV1/FVC < 75%
	FEV1/FVC > 85%			
Exacerbations requiring oral systemic glucocorticoids	0-1/year	≥ 2 in 1 year		
	Consider severity & interval since last exacerbation Frequency and severity may fluctuate over time for patients in any severity category Relative annual risk of exacerbations may be related to FEV1			

Asthma *Control* Classification:

	Classification of *Asthma Control* (12 years of age and older)		
	Well Controlled	Not Well Controlled	Very Poorly Controlled
Symptoms	≤ 2 days/week, but not more than once on each day	≥ 2 days/week or multiple times on ≤ 2 days/week	Throughout the day
Nighttime awakenings	≤ 1 day/month	≥ 2 times/month	≥ 2x/week
Interference with normal activities	None	Some limitation	Extremely limited
SABA use to control symptoms (not for EIB prevention	≤ 2 days/week	> 2 days/week	Several times/day
FEV1 or peak flow	> 80% predicted or personal best	60-80% predicted or personal best	< 60% predicted or personal best
FEV1/FVC	> 80%	75-80%	< 75%
Exacerbations requiring oral systemic glucocorticoids (Consider severity & interval since last exacerbation)	0-1/year	≥ 2/year: In general, more frequent and intense exacerbations (e.g., requiring urgent, unscheduled care, hospitalization, or ICU admission) indicate poorer disease control. For treatment purposes, patients who had ≥ 2 exacerbations requiring oral systemic glucocorticoids in the past year may be considered the same as patients who have persistent asthma, even in the absence of impairment levels consistent with persistent asthma.	
Asthma Control Test	≥ 20	16-19	≤ 15

Asthma control test: a validated set of questions
The Asthma Control Test provides a numerical score to help determine if your asthma symptoms are well controlled.
Step 1: Circle the number of each answer in the score box provided [ ].
Step 2: Add up each score in each box [ ] for the total.
Step 3: Take the completed test to your healthcare provider to talk about your score.

Asthma Control Test				
1. In the past 4 weeks, how much of the time did your asthma keep you from getting as much done at work, school or at home?				
All of the time [1]	Most of the time [2]	Some of the time [3]	A little of the time [4]	None of the time [5]
2. During the past 4 weeks, how often have you had shortness of breath?				

More than once a day [1]	Once a day [2]	3 to 6 times a week [3]	Once or twice a week [4]	Not at all [5]
3. During the past 4 weeks, how often did your asthma symptoms (wheezing, coughing, shortness of breath, chest tightness or pain) wake you up at night or earlier than usual in the morning?				
4 or more nights a week [1]	2 to 3 nights a week [2]	Once a week [3]	Once or twice [4]	Not at all [5]
4. During the past 4 weeks, how often have you used your rescue inhaler or nebulizer medication (such as albuterol)?				
3 or more times per day [1]	1 to 2 times per day [2]	2 or 3 times per week [3]	Once a week or less [4]	Not at all [5]
5. How would you rate your asthma control during the past 4 weeks?				
Not Controlled at all [1]	Poorly controlled [2]	Somewhat controlled [3]	Well controlled [4]	Completely controlled [5]
Total Score: _____				
Interpretation of Total Score: Well controlled: ≥ 20 Not well controlled: 16-19 Very poorly controlled: ≤ 15				

Dyspnea Scales:

Modified Medical Research Council (mMRC) Dyspnea Scale		**Medical Research Council (MRC) Dyspnea Scale**	
Grade	**Describe Breathlessness**	**Grade**	**Measures the degree of breathlessness related to activity**
0	I only get breathless with strenuous exercise	1	Not troubled by breathless except on strenuous exercise
1	I get short of breath when hurrying on level ground or walking up a slight hill	2	Short of breath when hurrying on a level or when walking up a slight hill
2	On level ground, I walk slower than people of the same age because of breathlessness or have to stop for breath when walking my own pace	3	Walks slower than most people on the level, stops after a mile or so, or stops after 15 minutes walking at own pace
3	I stop for breath after walking about 100 yards or after a few minutes on level ground	4	Stops for breath after walking 100 yards, or after a few minutes on level ground
4	I am too breathless to leave the house, or I am breathless when dressing	5	Too breathless to leave the house, or breathless when dressing/undressing

Exacerbations of COPD:

- Moderate exacerbations that required either systemic corticosteroids (intramuscular, intravenous, or oral) and/or antibiotics. One of the two required moderate exacerbations had to require the use of systemic corticosteroids.
- Severe exacerbations required hospitalization or observation >24 hours in emergency department/urgent care facility

Atopic Dermatitis:

Moderate atopic dermatitis – Areas of dry skin, frequent itching, redness (with or without excoriation and localized skin thickening); moderate impact on everyday activities and psychosocial wellbeing, frequently disturbed sleep.

Severe atopic dermatitis – Widespread areas of dry skin, continuous itching, redness (with or without excoriation, extensive skin thickening, bleeding, oozing, cracking, and alteration of pigmentation); severe limitation of everyday activities and psychosocial functioning, nightly loss of sleep.

PHARMACY COVERAGE GUIDELINE

DUPIXENT® (dupilumab) injection
Generic Equivalent (if available)

Atopic Dermatitis Therapies:

Topical corticosteroids (TCS):

- Low-potency corticosteroids are recommended for maintenance therapy
- Intermediate and high-potency corticosteroids should be used for the treatment of clinical exacerbation over short periods of time
- Ultra-high-potency corticosteroids should be used only for very short periods (1-2 weeks) and in non-facial non-skinfold areas.
- Do not use potent fluorinated corticosteroids on the face, eyelids, genitalia, and intertriginous areas or in young infants.

Topical calcineurin inhibitors (TCI):

- Tacrolimus ointment (Protopic and generics) is indicated as second-line therapy for moderate to severe atopic dermatitis
- Pimecrolimus cream (Elidel and generics) is indicated as second line therapy for mild to moderate atopic dermatitis

Topical phosphodiesterase 4 (PDE-4) inhibitor:

- Eucrisa (crisaborole) ointment is indicated for treatment of mild to moderate atopic dermatitis

Relative Potency of Selected Topical Corticosteroid Products:

Product	Dosage form	Strength
Category I – Very high potency		
Augmented betamethasone dipropionate	Gel, ointment	0.05
Clobetasol propionate	Ointment, gel, cream	0.05
Fluocinonide	Cream	0.1
Diflorasone diacetate	Ointment	0.05
Halobetasol propionate	Ointment, cream	0.05
Category II – High potency		
Amcinonide	Ointment, cream, lotion	0.1
Augmented betamethasone dipropionate	Cream, lotion	0.05
Betamethasone dipropionate	Ointment, cream	0.05
Betamethasone valerate	Ointment	0.1
Desoximetasone	Ointment, cream	0.25
Desoximetasone	Gel	0.05
Diflorasone diacetate	Ointment (emollient base), cream	0.05
Fluocinonide	Ointment, gel, cream	0.05
Halcinonide	Ointment, cream	0.1

Investigator Global Assessment Scale (IGA):

Validated-Investigator-Global-Assessment-Scale_vIGA-AD_2017.pdf (eczemacouncil.org) [Accessed October 09, 2021]

The IGA score is selected using the morphologic descriptors that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.

Score	Morphological Description
0 – Clear	No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present.

1 – Almost clear	Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting.
2 – Mild	Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting.
3 – Moderate	Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present.
4 – Severe	Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.
Notes: 1. In indeterminate cases, use extent to differentiate between scores. For example: • Patient with marked erythema (deep or bright red), marked papulation and/or marked lichenification that is limited in extent (instead of widespread), would be considered "3 – Moderate". 2. Excoriations should not be considered when assessing disease severity	

Eczema Area and Severity Index (EASI) score (A-E):
An EASI score is a tool used to measure the extent (area) and severity of atopic eczema. EASI score does not include a grade for dryness or scaling. Include only inflamed areas.

A. Body regions:
There are four body regions:

- Head and neck
  - Face occupies 33% (17% each side), neck 33% (17% front and back) and scalp 33% of the head and neck region
- Trunk (including genital area)
  - Front occupies 55% and back 45% of the trunk
- Upper limbs
  - Each arm occupies 50% of the upper limb region (front or back of one arm is 25%)
- Lower limbs (including buttocks)
  - Each leg occupies 45% (front or back of one leg is 22.5%) and buttocks 10% of the lower limbs region

B. Area score:
Area score is recorded for each of the four regions of the body. The area score is the percentage of skin affected by eczema for each body region.

Area score	Percentage of skin affected by eczema in each region
0	No active eczema in this region
1	1-9
2	10-29
3	30-49
4	50-69
5	70-89
6	90-100: the entire region is affected by eczema

C. Severity score:
Severity score is recorded for each of the four regions of the body. The severity score is the sum of the intensity scores for four signs. The four signs are:

1. Redness (erythema, inflammation)
2. Thickness (induration, papulation, swelling—acute eczema)
3. Scratching (excoriation)
4. Lichenification (lined skin, furrowing, prurigo nodules—chronic eczema).

The *average* intensity of each sign in each body region is assessed as: none (0), mild (1), moderate (2) and severe (3). Half scores are allowed. It may be difficult to assess redness in dark skin. If in doubt, increase the average redness score by one level.

Score	Intensity of redness, thickness/swelling, scratching. lichenification
0	None, absent
1	Mild (just perceptible)
2	Moderate (obvious)
3	Severe

D. Calculations:
For each region, record the intensity for each of four signs and calculate the severity score.

- Severity score = redness intensity + thickness intensity + scratching intensity + lichenification intensity

For each region, multiple the severity score by the area score and by a multiplier. The multiplier is different for each body site.

- Head and neck: severity score x area score x 0.1 (in children 0–7 years, x 0.2)
- Trunk: severity score x area score x 0.3
- Upper limbs: severity score x area score x 0.2
- Lower limbs: severity score x area score x 0.4 (in children 0–7 years, x 0.3)

Add up the total scores for each region to determine the final EASI score. The minimum EASI score is 0 and the maximum EASI score is 72.

E. Interpretation:
The suggested severity levels for the EASI are as follows:

0	Clear
0.1-1.0	Almost clear
1.1-7.0	Mild
7.1-21.0	Moderate
21.1-50.0	Severe
50.1-72.0	Very severe

Pruritus Numerical Rating Scale (NRS):
Numerical Rating Scale - Pruritus Resources (pruritussymposium.de) [Accessed October 09, 2021]
The NRS is comprised of one item and is represented by numbers 0 (“no itch”) to 10 (“worst imaginable itch”). Patients are asked to rate the intensity of their itch using this scale. It features high reliability and concurrent validity and is a popular choice for all patients due to its simple format. Time needed for completion: 1 minute. It has been validated in several languages.

- It can be interpreted as follows:
  - NRS 0 - no pruritus
  - NRS < 3 - mild pruritus
  - NRS ≥ 3 < 7 - moderate pruritus
  - NRS ≥ 7 < 9 - severe pruritus
  - NRS ≥ 9 - very severe pruritus

On a scale from 0 (no itch) to 10 (worst imaginable itch), how would you rate your itch overall (on average) during the past 24-hour? (Select number)										
0	1	2	3	4	5	6	7	8	9	10

Chronic rhinosinusitis:

Types of Chronic Rhinosinusitis:

Features	CRSwNP	CRSsNP	AFRS
Bilateral nasal polyps	Presence required for diagnosis*	Exclusion required for diagnosis	Yes, in most cases
Allergic mucin	May be present	May be present	Required for diagnosis
Aspirin associated respiratory disease	Asthma: present in 40% Aspirin intolerance & asthma present I 15%	Rare	May be present
IgE-mediated allergy to fungus	May be present	May be present	Required for diagnosis
* Unless medical record documents removal of bilateral nasal polyps during surgery CRSwNP: Chronic rhinosinusitis with nasal polyps CRSsNP Chronic rhinosinusitis without nasal polyps AFRS: Allergic fungal rhinosinusitis			

Chronic rhinosinusitis with nasal polyposis:

- Inflammation of the nose and paranasal sinuses characterized by the presence of two or more of the following symptoms for greater than 12-weeks duration:
  1) Nasal blockage/obstruction/congestion
  2) Nasal discharge
  3) Facial pain/pressure
  4) Reduction or loss of smell (hyposmia or anosmia)
- Confirmation of the diagnosis is made by sinus CT scan or nasal endoscopy to determine if there is nasal polyposis in both nasal passages

Prurigo nodularis (PN):

Investigator Global Assessment (IGA) for stage of chronic prurigo (CPG), chronic nodular prurigo (CNPG) and signs of activity in chronic prurigo		
Score	Category	Description
IGA-NCPG stage		
0	Clear	No nodules (0 nodules)
1	Almost clear	Rare palpable pruriginous nodules (approximately 1–5 nodules)

2	Mild	Few palpable pruriginous nodules (approximately 6–19 nodules)
3	Moderate	Many palpable pruriginous nodules (approximately 20–100 nodules)
4	Severe	Abundant palpable pruriginous nodules (over 100 nodules)
IGA-CPG stage		
0	Clear	No pruriginous lesions (0 lesions)
1	Almost clear	Rare palpable pruriginous lesions (approximately 1–5 lesions)
2	Mild	Few palpable pruriginous lesions (approximately 6–19 lesions)
3	Moderate	Many palpable pruriginous lesions (approximately 20–100 lesions)
4	Severe	Abundant palpable pruriginous lesions (over 100 lesions)
IGA-CPG Activity		
0	Clear	No pruriginous lesions have excoriations or crusts
1	Almost clear	Very small proportion of pruriginous lesions have excoriations or crusts (up to approximately 10% of all pruriginous lesions)
2	Mild	Minority of pruriginous lesions have excoriations or crusts (approximately 11–25% of all pruriginous lesions)
3	Moderate	Many pruriginous lesions have excoriations or crusts (approximately 26–75% of all pruriginous lesions)
4	Severe	Majority of pruriginous lesions have excoriations or crusts (approximately 76–100% of all pruriginous lesions)

Chronic Spontaneous Urticaria (CSU)
Weekly Itch Severity Score (ISS7)

- The ISS7 is the sum of the daily itch severity scores (dISS) over 7 days and ranges from 0 to 21
- The dISS is the average of the AM & PM scores on a scale of 0 (none) to 3 (severe) [0 = none; 1 = mild; 2 = moderate; 3 = severe]
- A higher itch severity score indicates more severe itching
- A negative change score indicates improvement
- Minimally important difference (MID) response in the ISS7
    - MID response is defined as a reduction ≥ 5 points in ISS7

Urticaria activity score over 7 days (UAS7) – a composite scoring

- The UAS7 is the sum of the daily urticarial activity scores (dUAS) over 7 days and ranges from 0 to 42
- The dUAS is the average of the AM & PM urticarial activity scores and ranges from 0 to 6
- The urticarial activity score is the sum of ratings on a scale of 0 to 3 (0 = none; 1 = mild; 2 = moderate; 3 = intense/severe) for:
    - (1) the number of wheals (hives)
        - 0 = none
        - 1 = mild (1-6 hives)
        - 2 = moderate (7-12 hives)
        - 3 = severe (more than 12 hives)
    - (2) itch intensity (ISS) over the previous 12 hours, ranges from 0 to 6, and is measured twice daily (morning & evening)
        - 0 = none

  - 1 = mild (present but not annoying or troublesome)
  - 2 = moderate (troublesome but does not interfere with normal daily activity or sleep)
  - 3 = intense (severe, sufficiently troublesome to interfere with normal daily activity or sleep)
- A higher urticarial activity score indicates more urticaria activity
- A negative change score indicates improvement
- Goal is UAS7 score $\leq$ 6
- Complete responder is UAS7 = 0

H1 Antihistamines:
- First-generation agents (e.g., hydroxyzine, diphenhydramine, chlorpheniramine)
- Second-generation agents (e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine)

H2 Antagonist:
- Cimetidine, famotidine

Leukotriene receptor antagonists:
- Montelukast, zafirlukast

Resources:

Dupixent (dupilumab) injection product information, revised by Regeneron Pharmaceuticals, Inc. 04-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed April 28, 2025.

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