

Pharmacy Policy Bulletin: J-0539 Dupixent (dupilumab) – Commercial and Healthcare Reform	
Number: J-0539	Category: Prior Authorization
Line(s) of Business: <input checked="" type="checkbox"/> Commercial <input checked="" type="checkbox"/> Healthcare Reform <input type="checkbox"/> Medicare	Benefit(s): Commercial: Prior Authorization (1.): 1. Miscellaneous Specialty Injectable = Yes w/ Prior Authorization Quantity Limits (1., 2., 3., or 4.): 1. Quantity Limits = Safety/Specialty 2. Quantity Limits = Safety/Specialty + Dose Opt 3. Quantity Limits = Safety/Specialty + Dose Opt + Watchful 4. Rx Mgmt Performance = MRXC = Yes Healthcare Reform: Not Applicable
Region(s): <input checked="" type="checkbox"/> All <input type="checkbox"/> Delaware <input type="checkbox"/> New York <input type="checkbox"/> Pennsylvania <input type="checkbox"/> West Virginia	Additional Restriction(s): None
Version: J-0539-027	Original Date: 03/14/2017
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Drugs Product(s):	<ul style="list-style-type: none"> Dupixent (dupilumab)
FDA-Approved Indication(s):	<ul style="list-style-type: none"> Treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids. 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. Add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP) Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE). Treatment of adult patients with prurigo nodularis (PN) Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype Treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment Treatment of adult patients with bullous pemphigoid (BP)

Background:

- Dupixent is a human monoclonal antibody targeting interleukin-4 (IL-4) and interleukin-13 (IL-13), inhibiting signaling of inflammatory cytokines that contribute to the signs and symptoms of atopic and inflammatory conditions.

Atopic Dermatitis

- Atopic dermatitis (AD) is a chronic, relapsing, pruritic inflammatory skin disease that occurs more commonly in children, but also affects many adults. AD is often associated with elevated serum immunoglobulin (IgE) levels and a personal or family history of type I allergies, allergic rhinitis, and asthma. Clinical features of AD include pruritus, skin dryness, erythema, oozing and crusting, and lichenification.
- According to the American Academy of Dermatology (AAD), topical corticosteroids are recommended for initial treatment of atopic dermatitis, followed by non-steroid therapies.
- Protopic (tacrolimus), Elidel (pimecrolimus), Eucrisa (crisaborole), and Opzelura (ruxolitinib) are non-steroid therapies for topical treatment of atopic dermatitis.
 - Elidel (pimecrolimus) cream 1% is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **mild-to-moderate** atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable.
 - Protopic (tacrolimus) ointment 0.03% (adults and children 2 years of age and older) and 0.1% (adults and children 16 years of age and older) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of **moderate-to-severe** atopic dermatitis in non-immunocompromised adults and children who have failed to respond adequately to other topical prescription treatments for atopic dermatitis, or when those treatments are not advisable.
 - Eucrisa (crisaborole) is a topical phosphodiesterase 4 (PDE-4) inhibitor indicated for topical treatment of **mild-to-moderate** atopic dermatitis in patients 3 months of age and older.
 - Opzelura (ruxolitinib) is a topical short-term and non-continuous chronic treatment of **mild-to-moderate** AD in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.
- Severity of atopic dermatitis is defined by the Validated Investigator's Static Global Assessment (v-IGA)
 - 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.

- Topical corticosteroids should be avoided if a patient has damaged skin, such as infected skin (unless advised by a doctor), rosacea, acne, and skin ulcers (open sores).
- For systemic therapies in AD, the AAD makes strong recommendations for the use of dupilumab, tralokinumab, abrocitinib, baricitinib, and upadacitinib. Conditional recommendations are made in favor of using phototherapy, azathioprine, cyclosporine, methotrexate, and mycophenolate, and against the use of systemic corticosteroids.
- Examples of positive clinical response in AD therapy include improvements in erythema, induration/papulation/edema, excoriations, and lichenification; reduced pruritus; decreased requirement for other topical or systemic therapies; reduced body surface area affected with AD.

Asthma

- Appropriate diagnosis of asthma (versus etiology of pulmonary fibrosis, for example, COPD or idiopathic pulmonary fibrosis) may be confirmed by measurement of FEV₁ reversibility after administration of albuterol. As a standard guideline, 12% or 200 mL is generally accepted as FEV₁ reversibility.
- The standard of care for moderate to severe asthma is maintenance use of a moderate- or high-dose inhaled corticosteroid (ICS) and long-acting beta agonist (LABA) ± oral corticosteroids taken as daily or alternate-day therapy.
- Eosinophilic phenotype asthma is associated with tissue and sputum eosinophilia, thickening of basement membrane zone, and often by response to corticosteroids.
- According to asthma guidelines, it is recommended to attempt to reduce systemic corticosteroid use when asthma is well controlled.
- Biologic therapy may be considered for moderate to severe asthma once maintenance treatment is optimized.
- The Global Initiative for Asthma (GINA) guidelines recommend biologic therapy in patients with uncontrolled, difficult-to-treat and severe asthma when optimized on a medium- or high-dose ICS with a second controller (usually a long-acting beta-2 agonist [LABA]). The GINA guidelines define uncontrolled asthma as 2 or more asthma exacerbations requiring oral corticosteroids or 1 or more asthma exacerbation requiring hospitalization.

Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients 6 to 11 years old

Drug	Low Dose	Moderate Dose	High Dose
Beclomethasone dipropionate (pMDI, standard particle, HFA)	100-200 mcg	> 200-400 mcg	> 400 mcg
Beclomethasone dipropionate (pMDI, extrafine particle, HFA)	50-100 mcg	> 100-200 mcg	> 200 mcg
Budesonide (DPI, or pMDI, standard particle, HFA)	100-200 mcg	> 200-400 mcg	> 400 mcg
Budesonide (nebulers)	250-500 mcg	>500-1000 mcg	>1000 mcg
Ciclesonide (pMDI, extrafine particle, HFA)	80 mcg	>80-160 mcg	>160 mcg

Fluticasone furoate (DPI)	50 mcg	50 mcg	n.a.
Fluticasone propionate (DPI)	50-100 mcg	> 100-200 mcg	> 200 mcg
Fluticasone propionate (pMDI, standard particle, HFA)	50-100 mcg	>100-200 mcg	>200 mcg
Mometasone furoate (pMDI, standard particle, HFA)	100 mcg	100 mcg	200 mcg

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

Estimated Comparative Daily Inhaled Corticosteroid Dosages for Patients ≥ 12 years old

Drug	Low Dose	Moderate Dose	High Dose
Beclomethasone dipropionate (pMDI, standard particle, HFA)	200-500 mcg	>500-1000 mcg	>1000 mcg
Beclomethasone dipropionate (DPI or pMDI, extrafine particle, HFA)	100-200 mcg	>200-400 mcg	>400 mcg
Budesonide (DPI, or pMDI, standard particle, HFA)	200-400 mcg	>400-800 mcg	>800 mcg
Ciclesonide (pMDI, extrafine particle, HFA)	80-160 mcg	>160-320 mcg	>320 mcg
Fluticasone furoate (DPI)	100 mcg	100 mcg	200 mcg
Fluticasone propionate (DPI)	100-250 mcg	>250-500 mcg	>500 mcg
Fluticasone propionate (pMDI, standard particle, HFA)	100-250 mcg	>250-500 mcg	>500 mcg
Mometasone furoate (DPI)	220 mcg	>220-440 mcg	>440-880 mcg
Mometasone furoate (pMDI, standard particle, HFA)	200-400 mcg	200-400 mcg	>400 mcg

Abbreviations: DPI: dry powder inhaler; HFA: hydrofluoroalkane propellant; pMDI: pressurized metered dose inhaler

Bullous Pemphigoid (BP)

- Bullous Pemphigoid (BP) is an autoimmune subepidermal blistering disease that presents as tense fluid filled sacs, severe pruritus and pain. BP often starts as a prodromal phase with the absence of blisters. Disease can progress over weeks to years to the bullous phase with fluid filled blisters or lesions that are usually bilateral and predominantly in skin creases or flexural areas of limbs and lower

trunk. Rarely BP has mucous membrane involvement. The average age for BP onset is 60 years and is much less common among younger adults and children. Drugs, such as gliptins and immune checkpoint inhibitors, potentially trigger BP. BP can be associated with neurological disorders such as multiple sclerosis and Parkinson's disease.

- Goals of treating BP are to treat skin eruptions, reduce itch, prevent/reduce risk of recurrence, and improve quality of life. 2022 European Academy of Dermatology and Venereology guidelines for BP consider as first choice potent to super potent topical corticosteroids for localized mild to moderate BP and recommend super potent topical corticosteroids or oral corticosteroids for non-localized mild to moderate disease or severe disease. Conventional immunosuppressants, such as methotrexate, azathioprine, or mycophenolate, may be considered for corticosteroid-dependent, relapsing, or treatment recalcitrant BP.
- Examples of high potency and super potency topical corticosteroids:

High Potency	Super High Potency
Amcinonide 0.1% ointment and cream	Betamethasone dipropionate augmented 0.05% ointment, lotion, gel
Betamethasone dipropionate augmented 0.05% cream	Clobetasol propionate 0.05% ointment, cream, lotion, gel, foam
Betamethasone dipropionate 0.05% ointment	Fluocinonide 0.1% cream
Desoximetasone 0.025% ointment, cream	Halobetasol propionate 0.05% ointment, cream
Desoximetasone 0.05% gel	
Fluocinonide 0.05% ointment, cream, gel, solution	
Halcinonide 0.1% ointment, cream solution	

Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

- Chronic rhinosinusitis (CRS) is defined as inflammation of the nose and paranasal sinuses that lasts for more than 12 weeks and usually responds incompletely to therapy, which may need to be continued long-term. There are 3 phenotypes of CRS: CRS with nasal polyps (CRSwNP), CRS without nasal polyps (CRSsNP), and allergic fungal rhinosinusitis (AFRS).
- According to the British Society for Allergy and Clinical Immunology (BSACI) guidelines, all patients should have a trial of medical treatment before surgery unless the nature of the polyps is in doubt.
- Smaller polyps may respond to intranasal corticosteroids only, initially betamethasone nasal drops. Larger polyps may respond to a medical polypectomy including prednisolone and betamethasone nasal drops.
- Other treatment options for CRSwNP include nasal saline, anti-leukotrienes, systemic corticosteroids, antibiotics, azelastine, aspirin desensitization, and sinus surgery.
- The Nasal Congestion Score is a patient reported tool used to measure changes in nasal congestion and obstruction. It ranges from 0 – 3, and is the monthly average of the daily morning AM patient-assessed daily symptom severity (0 = no symptoms to 3 = severe symptoms).
- The Nasal Polyp Score (NPS), the sum of right and left nostril scores, is a physician-reported assessment is used to characterize the patient's polyps from 0 = no polyps to 4 = severe disease with large polyps causing complete obstruction of the inferior nasal cavity. Each nostril is scored on a scale of 0 to 4, with the total score being the sum of left and right nostril scores (range: 0-8).

- Absolute eosinophil count = % Eosinophil x White blood cell count

Chronic obstructive pulmonary disease (COPD)

- COPD is a progressive lung disease that encompasses emphysema, chronic bronchitis, and refractory asthma. The airways in the lungs become inflamed and thicken. Lung tissue is destroyed causing less oxygen to enter the body, while carbon dioxide becomes more difficult to remove. COPD may deteriorate acutely over a period of hours or chronically over several days or longer. When this occurs, a re-evaluation of the COPD treatment should be reviewed immediately.
- The 2024 Global Initiative for Chronic Obstructive Lung Disease (GOLD) Guidelines categorize patients into three different categories (A, B and E), based on COPD symptoms and exacerbation frequency and severity. These categories help to guide treatment for patients. For group A patients, first-line drug therapy is a short- or long-acting bronchodilator. A long-acting bronchodilator is preferred unless the patient has only very occasional dyspnea. For group B patients, first-line drug therapy is combination therapy with a LAMA plus a LABA. For group E patients, first-line drug therapy is LABA/LAMA combination therapy. If the blood eosinophil count ≥ 300 cells/mcL, consider triple therapy with LAMA/LABA plus an ICS (LABA/LAMA/ICS). If the patient has a history of asthma or findings suggestive of comorbid asthma, addition of an ICS is mandatory, as management of these patients should primarily follow asthma guidelines.

Exacerbation History: ≥ 2 moderate exacerbations or ≥ 1 leading to hospital admission	E	
Exacerbation History: 0 or 1 moderate exacerbations (not leading to hospital admission)	A	B
	Symptoms: mMRC 0 to 1 or CAT < 10	Symptoms: mMRC ≥ 2 or CAT ≥ 10

- The GOLD grades and severity of airflow obstruction (note that this may be different from severity of the disease) in COPD is based on post-bronchodilator FEV₁.

COPD patients (FEV₁/FVC < 0.7)		
GOLD 1	Mild	FEV ₁ $\geq 80\%$ predicted
GOLD 2	Moderate	50% \leq FEV ₁ $\leq 80\%$ predicted
GOLD 3	Severe	30% \leq FEV ₁ $\leq 50\%$ predicted
GOLD 4	Very Severe	FEV ₁ < 30% predicted

- At an individual patient level, FEV₁ by itself is an unreliable marker of the severity of breathlessness, exercise limitation, health status impairment, and risk of exacerbation. Because there is a weak correlation between the severity of airflow obstruction and the symptoms experienced by the patient or the impairment of their health status, formal assessment of symptoms using validated questionnaires is required.
- The mMRC dyspnea scale is used to assess the degree of baseline functional disability due to dyspnea.

Chronic Spontaneous Urticaria (CSU)

- CSU is recurrent urticaria, angioedema or both for six weeks or longer. Urticaria is also known as hives or wheals. CSU is also known as chronic idiopathic urticaria (CIU). The underlying cause or systemic disease should be ruled out (for example, medications, recent travel, infections, systemic lupus erythematosus).

- The 2014 American Academy of Allergy, Asthma & Immunology and American College of Allergy, Asthma & Immunology guidelines consider second generation H1 antihistamines to be first line agents for chronic urticaria. Xolair is recommended as an alternative therapy for patients with refractory chronic urticaria.

Eosinophilic Esophagitis (EoE)

- EoE is a chronic, progressive, inflammatory disease characterized by esophageal dysfunction and eosinophilic infiltration. Chronic inflammation can lead to esophageal remodeling, fibrosis, and stricture formation. Symptoms of esophageal dysfunction can include dysphagia, food impaction, or chest pain.
- EoE is diagnosed by esophageal biopsy showing eosinophilic infiltration isolated to esophagus defined as ≥ 15 eosinophils/high power field (eos/hpf). Biopsies are taken from at least two different locations in the esophagus, typically in the distal and proximal portions of the esophagus.
- The histopathology of EoE is the same across age groups, however the symptom presentation differs. Pediatric patients 1 to 11 years of age with EoE may experience failure to thrive, abdominal pain, vomiting, regurgitation, food refusal, trouble swallowing, heartburn, and acid reflux. Adolescents and adults predominantly experience dysphagia.
- The 2020 American Gastroenterological Association (AGA) Institute and the Joint Task Force (JTF) on Allergy-Immunology Practice Parameters Clinical Guidelines for the Management of EoE recommend either PPIs (conditional; very low quality) or swallowed respiratory corticosteroids (strong; moderate quality) for patients with EoE as first-line pharmacologic therapies over no treatment.

Prurigo Nodularis (PN)

- PN is a rare, chronic, inflammatory disease that causes hard, itchy bumps on the skin. Firm nodules or bumps typically appear at around six weeks and are developed from constant itching or rubbing. Nodules can appear anywhere on the skin, but are typically found on the arms, legs, back, buttocks, or abdomen.
- Due to the potential symptom overlap with other dermatology conditions, a specialist (dermatologist, allergist, or immunologist) should diagnosis a patient to prevent misdiagnosis.
- The 2021 Practical Approaches for the Diagnosis and Management of PN is an expert panel consensus that provides a treatment ladder. This 4-tier treatment ladder addresses both neural and immunologic mechanisms. Patients can enter the treatment ladder at any tier based on clinical presentation and move up or down the ladder based on treatment response.
- For immunologic mechanisms, tier 1 recommendations include topical corticosteroids, topical calcitriol, topical calcineurin inhibitors, or intralesional corticosteroids (< 10 lesions)/cryotherapy; tier 2 recommendations include cyclosporine, methotrexate, or narrowband phototherapy; tier 3 recommendations include IL-31 inhibitors, azathioprine, or dupilumab; tier 4 recommendations include Janus kinase (JAK) inhibitors or mycophenolate mofetil.
- Prescribing Considerations:
 - Dupixent is not indicated for treatment of other eosinophilic conditions nor for relief of acute bronchospasm or status asthmaticus.
 - Patients should not utilize dual therapy with another monoclonal antibody.
 - Patients with pre-existing helminth infections should be treated prior to initiating therapy with these agents.
 - Administer by subcutaneous injection. The Dupixent pre-filled pen is for use in adults and pediatric patients aged 2 years and older. The Dupixent pre-

filled syringe is for use in adults and pediatric patients aged 6 months and older.

- Dupixent is not indicated for the relief of acute bronchospasm in COPD.
- Dupixent for treating BP is used in combination with a tapering course of oral corticosteroids. Gradually taper corticosteroids once disease control has occurred, after which continue Dupixent as monotherapy. In case of relapse, corticosteroids may be added if medically advisable.

Approval Criteria

I. Atopic Dermatitis

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met **(1. through 4.)**:

1. The member is 6 months of age or older.
2. The specialist (dermatologist, allergist or immunologist) submits attestation that the member has a diagnosis of atopic dermatitis (ICD-10: L20), that is moderate-to-severe.
3. The member meets one (1) of the following criteria **(a. or b.)**:
 - a. The member has experienced therapeutic failure or intolerance to one (1) of the following **(i. or ii.)**:
 - i. One (1) generic topical corticosteroid
 - ii. One (1) generic topical calcineurin inhibitor (specifically, tacrolimus or pimecrolimus)
 - b. The prescriber submits documentation the member has severe atopic dermatitis and topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following **(i. or ii.)**:
 - i. The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.
 - ii. Topical therapies are contraindicated due to severely damaged skin.
4. The requested quantity does not exceed the recommended dosing regimen per FDA label.

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved if the following criterion is met **(1.)**:

1. The prescriber attests that the member has experienced positive clinical response to therapy.

II. Asthma

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met **(1. through 7.)**:

1. The member is 6 years of age or older.
2. The member has a diagnosis of asthma (ICD-10: J82.83, J45.4, J45.5) that is moderate-to-severe.
3. The member meets one (1) of the following criteria **(a. or b.)**:
 - a. The member has a history of ≥ 2 asthma exacerbations requiring oral or injectable corticosteroid treatment in the previous 12 months.
 - b. The member has a history of ≥ 1 asthma exacerbation requiring hospitalization in the previous 12 months.
4. The member meets one (1) of the following criteria **(a. or b.)**:
 - a. Eosinophilic phenotype with documented blood eosinophils counts ≥ 150 cells/mcL
 - b. The member is currently taking daily or alternate-day oral corticosteroids
5. The member has inadequate symptom control despite regular treatment with medium- or high-dose inhaled corticosteroids (ICS) and at least one (1) additional asthma controller (for

- example, long-acting beta-2 agonist [LABA], leukotriene receptor antagonist [LTRA], or theophylline), with or without oral corticosteroids (OCS).
6. The member will continue treatment with medium- or high-dose ICS and at least one (1) additional asthma controller (for example, LABA, LTRA, or theophylline), with or without OCS, while using Dupixent.
 7. The requested quantity does not exceed the recommended dosing regimen per FDA label.

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved when one (1) of the following criteria is met (**1. through 4.**):

1. The prescriber attests that the member has decreased rescue medication or OCS use.
2. The prescriber attests that the member has had a decrease in frequency of severe asthma exacerbations.
3. The prescriber attests that the member experienced an increase in pulmonary function from baseline (for example, FEV₁).
4. The prescriber attests that the member has experienced a reduction in reported asthma-related symptoms (for example, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing).

III. Bullous Pemphigoid (BP)

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met (**1., 2., and 3.**):

1. The member is 18 years of age or older.
2. The specialist (dermatologist, allergist, or immunologist) submits attestation that the member has a diagnosis of BP.
3. The member has experienced therapeutic failure, contraindication, or intolerance to one (1) of the following (**a. or b.**):
 - a. High potency to super high potency topical corticosteroids.
 - b. Oral corticosteroids

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved when one (1) of the following criteria is met (**1. through 4.**):

1. The member has experienced disease control (for example, no new lesions and existing lesions are beginning to heal).
2. The member has experienced a reduction in the number of relapses.
3. The member has experienced improvement in BP symptoms.
4. The member has experienced a reduction in oral corticosteroid use.

IV. Chronic Obstructive Pulmonary Disease (COPD)

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met (**1. through 7.**):

1. The member is 18 years of age and older.
2. The member has a diagnosis of COPD (ICD-10: J41-J44).
3. The member has a post-bronchodilator FEV₁ ≤ 80% predicted
4. The member meets one (1) of the following criteria (**a. or b.**):
 - a. The member has a blood eosinophilic count of ≥ 300 cells/mcL
 - b. The member is currently taking daily or alternate-day oral corticosteroids
5. The member has a modified Medical Research Council dyspnea scale score of ≥ 2
6. The member meets one (1) of the following criteria (**a., b., or c.**):
 - a. An exacerbation history of at least two (2) moderate exacerbations resulting in treatment with systemic corticosteroids and/or antibiotics in the previous year

- b. One (1) severe exacerbation resulting in hospitalization or observation in the emergency department for over 24 hours in the previous year
 - c. GOLD group E
- 7. The member has inadequate symptom control despite regular treatment for at least 3 months with triple therapy consisting of a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (LAMA/LABA/ICS), unless intolerant of, or has contraindications to these agents.

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved when one (1) of the following criteria is met **(1. through 4.)**:

- 1. The prescriber attests that the member has experienced a reduction in symptoms of COPD.
- 2. The prescriber attests that the member has experienced an improvement in exercise tolerance.
- 3. The prescriber attests that the member has experienced delayed disease progression.
- 4. The prescriber attests that the member has experienced a reduction in the number of exacerbations.

V. Chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met **(1. through 5.)**:

- 1. The member is 12 years of age or older.
- 2. The member has a diagnosis of chronic rhinosinusitis with nasal polyposis (ICD-10: J33.9, J32.9).
- 3. The prescriber submits documentation of the patient's baseline bilateral nasal polyp score.
- 4. The prescriber submits documentation of the patient's baseline nasal congestion score.
- 5. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following **(a. and b.)**:
 - a. Intra-nasal corticosteroid
 - b. 14 day course of oral corticosteroids

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved when one (1) of the following criteria is met **(1. or 2.)**:

- 1. The prescriber attests that the member has a decrease in their nasal polyp score.
- 2. The prescriber attests that the member has a reduction in their nasal congestion/obstruction severity score.

VI. Chronic Spontaneous Urticaria (CSU)

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all the following criteria are met **(1., 2., and 3.)**:

- 1. The member is 12 years of age or older.
- 2. The member has a diagnosis of urticaria (ICD-10: L50.0, L50.1, L50.8, L50.9), classified as chronic spontaneous urticaria.
- 3. The member has experienced therapeutic failure, contraindication, or intolerance to one (1) second-generation non-sedating H1 antihistamine at the maximum recommended doses (for example: cetirizine, desloratadine, levocetirizine).

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved when the following criterion is met (1.):

1. The member has experienced improvement in CSU symptoms.

VII. Eosinophilic Esophagitis (EoE)

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met (1. through 5.):

1. The member has a diagnosis of EoE (ICD-10: K20.0).
2. The member weighs at least 15 kg.
3. The member meets one (1) of the following criteria (a. or b.):
 - a. The member is 1 to 11 years of age and meets the following criterion (i.):
 - i. The prescriber attests the member has a history of EoE signs or symptoms.
 - b. The member is 12 years of age or older and meets the following criterion (i.):
 - i. The prescriber attests the member has experienced two or more episodes of dysphagia per week.
4. The prescriber submits documentation that the member has an esophageal eosinophil count of ≥ 15 eos/hpf on esophageal biopsy.
5. The member has experienced therapeutic failure, contraindication, or intolerance to high-dose proton-pump inhibitor (PPI) therapy (for example, omeprazole or pantoprazole 80 mg/day).

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved when one (1) of the following criteria are met (1. or 2.):

1. The prescriber submits documentation that the member has experienced histological remission (specifically, < 15 eos/hpf) on esophageal biopsy.
2. The prescriber attests that the member has experienced reduced severity or frequency of clinical symptoms of esophageal dysfunction (for example, dysphagia, food impaction, gastroesophageal reflux).

VIII. Prurigo Nodularis (PN)

A. Initial Authorization

When a benefit, coverage of Dupixent may be approved when all of the following criteria are met (1. through 4.):

1. The member is 18 years of age or older.
2. The specialist (dermatologist, allergist, or immunologist) submits attestation that the member has a diagnosis of prurigo nodularis (PN) (ICD-10: L28.1).
3. The member has ≥ 10 identifiable nodular lesions.
4. The member meets one (1) of the following criteria (a. or b.):
 - a. The member has experienced therapeutic failure, contraindication, or intolerance to one (1) generic topical corticosteroid
 - b. The prescriber submits documentation topical therapy would not be advisable for maintenance therapy as evidenced by one (1) of the following (i. or ii.):
 - i. The member is incapable of applying topical therapies due to the extent of body surface area (BSA) involvement.
 - ii. Topical therapies are contraindicated due to severely damaged skin.

B. Reauthorization

When a benefit, reauthorization of Dupixent may be approved if one (1) of the following criteria are met (1. or 2.):

1. The prescriber attests that the member has experienced a reduction in itch from baseline.
2. The member has experienced a reduction in number of nodules or lesions from baseline.

IX. Quantity Limitations

When prior authorization is approved, Dupixent may be authorized in quantities as follows:

Diagnosis	Induction Therapy	Maintenance Therapy
Atopic Dermatitis (6 months to 5 years of age) (5 kg - < 15 kg)²	N/A	One (1) 200 mg pen/syringe every four (4) weeks
Atopic Dermatitis (6 months to 5 years of age) (15 kg - < 30 kg)²	N/A	One (1) 300 mg pen/syringe every four (4) weeks
Atopic Dermatitis (6-17 years of age) (15 kg - < 30 kg)	Two (2) 300 mg pens/syringes within the first four (4) weeks of therapy	One (1) 300 mg pens/syringes every four (4) weeks
Atopic Dermatitis (6-17 years of age) (30 kg - < 60 kg)	Four (4) 200 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 200 mg pens/syringes every four (4) weeks
Atopic Dermatitis (6-17 years of age) (≥ 60 kg)	Four (4) 300 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 300 mg pens/syringes every four (4) weeks
Atopic Dermatitis (≥ 18 years of age)	Four (4) 300 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 300 mg pens/syringes every four (4) weeks
Asthma (≥ 12 years of age)	Four (4) 200 mg or 300 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 200 mg or 300 mg pens/syringes every four (4) weeks
Asthma (6-11 years of age) (≥ 30 kg)¹	N/A	Two (2) 200 mg pens/syringes every four (4) weeks
Asthma (6-11 years of age) (15 kg - <30 kg)¹	N/A	One (1) 300 mg pen/syringe every four (4) weeks
CRSwNP, COPD	N/A	Two (2) 300 mg pens/syringes every four (4) weeks
EoE (15 kg - <30 kg)²	N/A	Two (2) 200 mg pens/syringes every four (4) weeks
EoE (30 kg - <40 kg)	N/A	Two (2) 300 mg pens/syringes every four (4) weeks

EoE (≥ 40 kg)³	N/A	Four (4) 300 mg pens/syringes every four (4) weeks
PN, BP	Four (4) 300 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 300 mg pens/syringes every four (4) weeks
CSU (≥ 18 years of age)	Four (4) 300 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 300 mg pens/syringes every four (4) weeks
CSU (12-17 years of age) (≥ 60 kg)	Four (4) 300 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 300 mg pens/syringes every four (4) weeks
CSU (12-17 years of age) (30 kg - < 60 kg)	Four (4) 200 mg pens/syringes within the first four (4) weeks of therapy	Two (2) 200 mg pens/syringes every four (4) weeks

N/A: Not applicable

¹ For pediatric patients (6-11 years old) with asthma and co-morbid moderate-to-severe atopic dermatitis, follow the recommended dosage for atopic dermatitis for this age population which includes an initial loading dose.

² Dupixent pre-filled pen is only for use in adults and pediatric patients aged 2 years and older

³ Patients diagnosed with EoE weighing ≥ 40 kg may receive weekly dosing of Dupixent.

- X.** Coding of quantity level limitations is at the maintenance therapy threshold. Claims for quantities of Dupixent pre-filled syringes or pens that exceed maintenance therapy limitations will reject at point of sale. Patient Level Authorization (PLA) will be needed for authorized quantities of pre-filled syringes or pens that exceed maintenance therapy limitations (specifically, induction therapy).
- XI.** If the patient has already had a trial of at least one (1) biologic agent for the same indication, the patient is not required to “step back” and try a nonbiologic agent.
- XII.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

- I.** Coverage of drugs addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.
- II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Initial Authorization

- Commercial and HCR Plans: If approved, up to a 6 month authorization may be granted.

Note: For Delaware Commercial fully-insured and ACA members, a 12 month authorization must be granted pursuant to 18 Del. C. §§3376(a) and 3586(a) and market conduct examination docket #5467 (Exam Authority #53287-22-701).

- Note: For induction therapy authorization duration, refer to the Quantity Limitations tables for the respective drug and diagnosis.

Reauthorization

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

Automatic Approval Criteria

None.

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Pharmacy policies do not constitute medical advice, nor are they intended to govern physicians' prescribing or the practice of medicine. They are intended to reflect the plan's coverage and reimbursement guidelines. Coverage may vary for individual members, based on the terms of the benefit contract.

The plan retains the right to review and update its pharmacy policy at its sole discretion. These guidelines are the proprietary information of the plan. Any sale, copying or dissemination of the pharmacy policies is prohibited; however, limited copying of pharmacy policies is permitted for individual use.