Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

Dupixent (dupilumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Dupixent (dupilumab) 200 mg/1.14 mL* Dupixent (dupilumab) 300 mg/2 mL*	2 pre-filled syringes/pens per 28 days

***Initiation of therapy: May approve two additional 200 mg/1.14 mL OR 300 mg/2 mL pre-filled syringes/pens in the first month of therapy for initiation dose for the indication of atopic dermatitis or asthma.**

APPROVAL CRITERIA

Initial requests for Dupixent (dupilumab) for the treatment of asthma may be approved if the following criteria are met:

I. Individual is 12 years of age or older; **AND**
II. Individual has a diagnosis of moderate-to-severe asthma as demonstrated by the following (NHLBI 2007):
    A. A pretreatment forced expiratory volume in 1 second (FEV_1) less than or equal to (≤) 80% predicted; **AND**
    B. FEV_1 reversibility of at least 12% and 200 milliliters (ml) after albuterol (salbutamol) administration; **AND**
III. One of the following:
    A. Individual has a blood eosinophil count (in the absence of other potential causes of eosinophilia, including hypereosinophilic syndromes, neoplastic disease, and known or suspected parasitic infection) greater than or equal to 150 cells/microliter [1 microliter (µL) is equal to 1 cubic millimeter (mm^3)] at initiation of therapy; **AND**
    B. Individual has had a 3 month trial and inadequate response or intolerance to combination controller therapy (high dose inhaled corticosteroids plus long acting $beta_2$ –agonists, leukotriene modifiers, theophylline or oral corticosteroids) (ERS/ATS 2013, GINA2019);

    OR
    C. Individual has oral corticosteroid dependent asthma; **AND**

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Applicable	X	X	X	X	X	X

D. Individual has had a 3 month trial and inadequate response or intolerance to high dose inhaled corticosteroid with daily oral glucocorticoids given in combination with a controller medication (either a long-acting $beta_2$-agonist, **or** leukotriene receptor antagonist, **or** theophylline) (ERS/ATS 2013, GINA2019);

AND

IV. Individual has experienced two or more asthma exacerbations in the prior 12 months requiring use of a systemic corticosteroid **or** temporary increase in the individual's usual maintenance dosage of oral corticosteroids (Castro 2018, Rabe 2018).

Continuation of therapy with Dupixent (dupilumab) after 12 months may be approved if the following criteria are met:

I. Individual has experienced one or more of the following:
   A. Decreased utilization of rescue medications; **OR**
   B. Decreased frequency of exacerbations (defined as worsening of asthma that requires an increase in inhaled corticosteroid dose or treatment with systemic corticosteroids); **OR**
   C. Increase in predicted FEV_1 from pretreatment baseline; **OR**
   D. Reduction in reported asthma-related symptoms, such as, asthmatic symptoms upon awakening, coughing, fatigue, shortness of breath, sleep disturbance, or wheezing.

Requests for Dupixent (dupilumab) for the treatment of atopic dermatitis may be approved when the following criteria are met:

I. Individual is 6 years or older; **AND**
II. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
III. Individual meets *one* of the following (A or B):
   A. Failure of topical pharmacological therapy as indicated by **both** (1 and 2) of the following:
      1. Daily treatment of topical corticosteroids of medium to higher potency for at least fourteen (14) days has failed to achieve and maintain remission of low or mild disease activity state; **OR**

Market Applicability						
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Applicable	X	X	X	X	X	X

a. Topical corticosteroids are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (AAD 2014):
   i. Individual has lesions located in sensitive areas (including, but not limited to, face, anogenital area or skin folds); **OR**
   ii. Individual has steroid-induced atrophy; **OR**
   iii. History of long-term or uninterrupted topical steroid use;

AND

2. Daily treatment of topical calcineurin inhibitors for six (6) weeks has failed to achieve and maintain remission of low or mild disease activity state; **OR**
   a. Topical calcineurin inhibitors (TCI) are not indicated due to severe hypersensitivity reactions or concomitant clinical situations, including but not limited to (Elidel 2017, Protopic 2019):
      i. History of or active malignant or pre-malignant skin conditions; **OR**
      ii. Individual has Netherton's Syndrome or other skin diseases that can increase the risk of systemic absorption of TCI; **OR**
      iii. Individual is considered to be immunocompromised, including those on systemic immunosuppressive medications on an ongoing basis;

OR

B. One of the following:
   1. Phototherapy (UVB or PUVA) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated; **OR**
   2. Systemic treatment (for example, corticosteroid or immunosuppressants) has failed to achieve and maintain remission of low or mild disease activity state or is contraindicated.

Requests for Dupixent (dupilumab) for the treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP) may be approved if the following criteria are met:

I. Individual is age 18 years and older; **AND**
II. Individual has a diagnosis of CRSwNP confirmed by one of the following (AAO-HNSF 2015):
   A. Anterior rhinoscopy; **OR**
   B. Nasal endoscopy; **OR**
   C. Computed tomography (CT); **AND**
III. Individual has had recent trial and inadequate response to maintenance intranasal corticosteroids (AAO-HNSF 2015); **AND**

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

IV. Individual is refractory to, or is ineligible or intolerant to the following:
   A. Systemic corticosteroids; **OR**
   B. Sino-nasal surgery; **AND**

V. Individual is requesting Dupixent (dupilumab) as add-on therapy to maintenance intranasal corticosteroids.

Requests for Dupixent (dupilumab) may not be approved when the above criteria are not met and for all other indications.

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This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

Market Applicability						
Market	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X

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Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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