Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Dupixent (dupilumab)

Override(s)	Approval Duration
Prior Authorization	1 year

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

***Initiation of therapy: May approve one additional 200 mg/1.14 mL OR 300 mg/2 mL pre-filled syringes in the first month of therapy for initiation dose.**

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 (medium to high dose inhaled corticosteroids plus long acting beta2 –agonists, leukotriene modifiers, theophylline or oral corticosteroids);

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

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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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 beta2-agonist, **or** leukotriene receptor antagonist, **or** theophylline);

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.

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 age 18 years or older; **AND**
II. Individual has a diagnosis of moderate to severe atopic dermatitis; **AND**
III. Chronic atopic dermatitis has been present for 3 years or more; **AND**
IV. Failure of topical pharmacological therapy as indicated by **one or more** of the following:
   A. Daily treatment of topical corticosteroids of medium to higher potency for the maximum treatment period indicated in the product prescribing information has failed to achieve and maintain remission of low or mild disease activity state; **OR**

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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B. Topical calcineurin inhibitors if topical corticosteroids are not indicated*, for the maximum treatment period indicated in the product prescribing information has failed to achieve and maintain remission of low or mild disease activity state; **OR**
C. Topical treatment is medically inadvisable as defined by treatments which have side effects or safety concerns which outweigh potential treatment benefits as evidenced by **any** of the following:
    1. Intolerance to treatment
    2. Hypersensitivity reactions
    3. Significant skin atrophy
    4. Systemic effects;

AND

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

* Topical corticosteroids may not be indicated in the following concomitant clinical situations:
    A. Individual has lesions located in sensitive areas (such as face, anogenital area or skin folds)
    B. Individual has steroid-induced atrophy
    C. History of long-term or uninterrupted topical steroid use

State Specific Mandates		
State name N/A	Date effective N/A	Mandate details (including specific bill if applicable) N/A

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 6, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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.
CRX-ALL-0365-19

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Eichenfield L. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. Journal of the American Academy of Dermatology. 2014-01;71:116.
6. Blauvelt A, de Bruin-Weller M, Gooderham M, et al. Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo controlled, phase 3 trial. Lancet. 2017; 389(10086):2287-2303.
7. Castro M, Corren J, Pavord J, et al. Dupilumab efficacy and safety in moderate to severe asthma. *New Engl J Med*. 2018; 378:2486-96.
8. Rabe KF, Nair P, Brusselle G, et al. Efficacy and safety of dupilumab in glucocorticoid-dependent severe asthma. *New Engl J Med*.2018; 378:2475-85.
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11. Dupixent (dupilumab) injection, for subcutaneous use [Product Information] Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2018.