UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2116-19
Program	Prior Authorization/Medical Necessity
Medications	Dupixent® (dupilumab)
P&T Approval Date	1/2017, 5/2017, 7/2017, 7/2018, 12/2018, 4/2019, 10/2019, 4/2020, 5/2020, 6/2020, 6/2021, 12/2021, 2/2022, 7/2022, 11/2022, 3/2023, 7/2023, 3/2024, 11/2024
Effective Date	2/1/2025

1. Background:

Dupixent® (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for treatment of 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. Dupixent can be used with or without topical corticosteroids. Dupixent is also indicated as an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma, as an add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP), for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE), for adult patients with prurigo nodularis (PN), and as add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Limitation of Use:

Dupixent is not for the relief of acute bronchospasm or status asthmaticus.

2. Coverage Criteria[a]:

A. <u>Atopic Dermatitis</u>

1. **<u>Initial Authorization</u>**

a. **Dupixent** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of moderate-to-severe chronic atopic dermatitis

-AND-

(2) History of failure, contraindication, or intolerance to **<u>two</u>** of the following therapeutic classes of topical therapies (document drug, date of trial, and/ or contraindication to medication)^**:**

(a) Medium,high, or very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]

(b) Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)].*
(c) Eucrisa (crisaborole)*

-AND-

(3) Patient is not receiving Dupixent in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(4) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Dupixent therapy

-AND-

(2) Patient is not receiving Dupixent in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(3) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

B. Asthma

1. **Initial Authorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Diagnosis of moderate-to-severe asthma

-AND-

(2) Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following:

(a) Poor symptom control (e.g., Asthma Control Questionnaire [ACQ] score consistently greater than 1.5 or Asthma Control Test [ACT] score consistently less than 20)
(b) Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
(c) Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
(d) Airflow limitation (e.g., after appropriate bronchodilator withhold forced expiratory volume in 1 second [FEV1] less than 80% predicted [in the face of reduced FEV1/forced vital capacity [FVC] defined as less than the lower limit of normal])
(e) Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(3) **One** of the following:

(a) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting that asthma is an eosinophilic phenotype as defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level ≥ 150 cells/μL

-OR-

(b) Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

(4) Dupixent will be used in combination with **one** of the following:

(a) **One** maximally dosed (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA) [e.g., Advair/AirDuo Respiclick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

(b) Combination therapy including **both** of the following:

i. **One** maximally dosed (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

-AND-

ii. **One** additional asthma controller medication [e.g., LABA - olodaterol (Striverdi) or indacaterol (Arcapta); leukotriene receptor antagonist – montelukast (Singulair); theophylline]

-AND-

(5) Patient is not receiving Dupixent in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(6) Prescribed by **one** of the following:

(a) Allergist
(b) Immunologist
(c) Pulmonologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Dupixent therapy as demonstrated by at least one of the following:

(a) Reduction in the frequency of exacerbations
(b) Decreased utilization of rescue medications
(c) Increase in percent predicted FEV1 from pretreatment baseline
(d) Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)
(e) Reduction in oral corticosteroid requirements

-AND-

(2) Dupixent is being used in combination with an ICS-containing maintenance medication [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta

(fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-AND-

(3) Patient is not receiving Dupixent in combination with any of the following:

(a) Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(4) Prescribed by **one** of the following:

(a) Allergist
(b) Immunologist
(c) Pulmonologist

Authorization will be issued for 12 months.

C. Chronic Rhinosinusitis with Nasal Polyposis

1. **Initial Authorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP) defined by **all** of the following:

(a) **Two or more** of the following symptoms for longer than 12 weeks duration:

i. Nasal mucopurulent discharge
ii. Nasal obstruction, blockage, or congestion
iii. Facial pain, pressure, and/or fullness
iv. Reduction or loss of sense of smell

-AND-

(b) **One** of the following findings using nasal endoscopy and/or sinus computed tomography (CT):

i. Purulent mucus or edema in the middle meatus or ethmoid regions
ii. Polyps in the nasal cavity or the middle meatus
iii. Radiographic imaging demonstrating mucosal thickening or partial or complete opacification of paranasal sinuses

-AND-

(c) **One** of the following:

i. Presence of bilateral nasal polyposis
ii. Patient has previously required surgical removal of bilateral nasal polyps

-AND-

(d) **One** of the following:

i. Patient has required prior sinus surgery
ii. Patient has required systemic corticosteroids (e.g., prednisone, methylprednisolone) for CRSwNP in the previous 2 years
iii. Patient has been unable to obtain symptom relief after trial of two of the following classes of agents^:
- Nasal saline irrigations
- Intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone)
- Antileukotriene agents (e.g., montelukast, zafirlukast, zileuton)

-AND-

(2) Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

-AND-

(3) Patient is **not** receiving Dupixent in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(4) Prescribed by **one** of the following:

(a) Allergist
(b) Immunologist
(c) Otolaryngologist
(d) Pulmonologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Dupixent therapy

-AND-

(2) Patient will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids (e.g., fluticasone, mometasone, triamcinolone).

-AND-

(3) Patient is **not** receiving Dupixent in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(4) Prescribed by **one** of the following:

(a) Allergist
(b) Immunologist
(c) Otolaryngologist
(d) Pulmonologist

Authorization will be issued for 12 months.

D. Eosinophilic Esophagitis

1. **Initial Authorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Diagnosis of eosinophilic esophagitis

-AND-

(2) Patient is experiencing symptoms related to esophageal dysfunction (e.g., dysphagia, food impaction, chest pain that is often centrally located and may not respond to antacids, gastroesophageal reflux disease-like symptoms/refractory heartburn, upper abdominal pain)

-AND-

(3) Submission of medical records (e.g., chart notes, laboratory values, etc.) documenting eosinophil-predominant inflammation on esophageal biopsy,

consisting of a peak value of ≥15 intraepithelial eosinophils per high power field (HPF) (or 60 eosinophils per mm^2)

-AND-

(4) Secondary causes of esophageal eosinophilia have been ruled out

-AND-

(5) Mucosal eosinophilia is isolated to the esophagus and symptoms have persisted after an 8-week trial of at least **one** of the following:[b]

(a) Proton pump inhibitors (e.g., pantoprazole, omeprazole)
(b) Topical (esophageal) corticosteroids (e.g., budesonide, fluticasone)

-AND-

(6) Patient is not receiving Dupixent in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(7) Prescribed by **one** of the following:

(a) Gastroenterologist
(b) Allergist

Authorization will be issued for 6 months.

2. **Reauthorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Dupixent therapy as evidenced by improvement of at least **one** of the following from baseline:

(a) Symptoms (e.g., dysphagia, chest pain, heartburn)
(b) Histologic measures (e.g., esophageal intraepithelial eosinophil count)
(c) Endoscopic measures (e.g., edema, furrows, exudates, rings, strictures)

-AND-

(2) Patient is not receiving Dupixent in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(3) Prescribed by or in consultation with a gastroenterologist or allergist

Authorization will be issued for 6 months.

E. Prurigo Nodularis

1. **Initial Authorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Diagnosis of prurigo nodularis

-AND-

(2) Patient has greater than or equal to 20 nodular lesions

-AND-

(3) History of failure, contraindication, or intolerance to previous prurigo nodularis treatment(s) (e.g., topical corticosteroids, topical calcineurin inhibitors, topical capsaicin)

-AND-

(4) Patient is not receiving Dupixent in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(5) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 6 months.

2. **Reauthorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Dupixent therapy

-AND-

(2) Patient is not receiving Dupixent in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

-AND-

(3) Prescribed by **one** of the following:

(a) Dermatologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

F. Chronic Obstructive Pulmonary Disorder (COPD)

1. **Initial Authorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Diagnosis of COPD

-AND-

(2) Submission of medical records (e.g., chart notes) documenting **all** of the following:

(a) Post-bronchodilator forced expiratory volume (FEV_1) / forced vital capacity (FVC) ratio less than 0.7
(b) Post-bronchodilator FEV_1 % predicted greater than or equal to 30% and less than or equal to 70%
(c) Patient has an eosinophilic phenotype defined by a baseline (pre-dupilumab treatment) peripheral blood eosinophil level ≥ 300 cells/µL

-AND-

(3) Uncontrolled or inadequately controlled COPD demonstrated by **both** of the following:

(a) **One** of the following:

i. Two or more COPD exacerbations in the previous year requiring treatment with systemic corticosteroids and/or antibiotics
ii. One or more COPD exacerbation(s) that resulted in hospitalization or observation for over 24 hours in an emergency department or urgent care facility in the past year

-AND-

(b) COPD exacerbation(s) occurred while receiving maintenance therapy with **one** of the following:

i. Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
ii. Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

-AND-

(4) Symptoms of chronic productive cough for at least 3 months in the past year

-AND-

(5) Dupixent will be used as add-on maintenance therapy in combination with **one** of the following:

(a) Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
(b) Dual therapy with a LAMA and LABA (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

-AND-

(6) Patient is not receiving Dupixent in combination with **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(7) Prescribed by **one** of the following:

(a) Allergist
(b) Immunologist

(c) Pulmonologist

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Dupixent** will be approved based on **all** of the following criteria:

(1) Documentation of a positive clinical response to Dupixent therapy as demonstrated by at least **one** of the following:

(a) Reduction in the frequency of COPD exacerbations
(b) Increase in percent predicted FEV1 from pretreatment baseline
(c) Reduction in severity or frequency of COPD-related symptoms (e.g., dyspnea, wheezing, cough, sputum volume, decrease in sputum purulence)
(d) Reduction in oral corticosteroid requirements

-AND-

(2) Dupixent is being used add-on maintenance therapy in combination with **one** of the following:

(a) Triple therapy with a long-acting muscarinic antagonist (LAMA), long-acting beta agonist (LABA), and inhaled corticosteroid (ICS) (e.g., Breztri Aerosphere, Trelegy Ellipta)
(b) Dual therapy with a long-acting muscarinic antagonist (LAMA) and long-acting beta agonist (LABA) (e.g., Anoro Ellipta, Bevespi Aerosphere, Stiolto Respimat) and a failure, contraindication, or intolerance to an inhaled corticosteroid (ICS)

-AND-

(3) Patient is not receiving Dupixent in combination with any of the following:

(a) Anti-interleukin-5 therapy [e.g., Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

-AND-

(4) Prescribed by **one** of the following:

(a) Allergist
(b) Immunologist
(c) Pulmonologist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.
^Tried/failed alternative(s) are supported by FDA labeling.
* Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

Table 1: Relative potencies of topical corticosteroids[3]

Class	Drug	Dosage Form	Strength (%)
Very high potency	Augmented betamethasone dipropionate	Ointment, gel	0.05
	Clobetasol propionate	Cream, foam, ointment	0.05
	Diflorasone diacetate	Ointment	0.05
	Halobetasol propionate	Cream, ointment	0.05
High Potency	Amcinonide	Cream, lotion, ointment	0.1
	Augmented betamethasone dipropionate	Cream, lotion	0.05
	Betamethasone dipropionate	Cream, foam, ointment, solution	0.05
	Desoximetasone	Cream, ointment	0.25
	Desoximetasone	Gel	0.05
	Diflorasone diacetate	Cream	0.05
	Fluocinonide	Cream, gel, ointment, solution	0.05
	Halcinonide	Cream, ointment	0.1
	Mometasone furoate	Ointment	0.1
	Triamcinolone acetonide	Cream, ointment	0.5
Medium potency	Betamethasone valerate	Cream, foam, lotion, ointment	0.1
	Clocortolone pivalate	Cream	0.1
	Desoximetasone	Cream	0.05
	Fluocinolone acetonide	Cream, ointment	0.025
	Flurandrenolide	Cream, ointment, lotion	0.05
	Fluticasone propionate	Cream	0.05
	Fluticasone propionate	Ointment	0.005
	Mometasone furoate	Cream, lotion	0.1
	Triamcinolone acetonide	Cream, ointment, lotion	0.1
Lower-medium potency	Hydrocortisone butyrate	Cream, ointment, solution	0.1
	Hydrocortisone probutate	Cream	0.1
	Hydrocortisone valerate	Cream, ointment	0.2
	Prednicarbate	Cream	0.1
Low potency	Alclometasone dipropionate	Cream, ointment	0.05
	Desonide	Cream, gel, foam, ointment	0.05
	Fluocinolone acetonide	Cream, solution	0.01
Lowest potency	Dexamethasone	Cream	0.1
	Hydrocortisone	Cream, lotion, ointment, solution	0.25, 0.5, 1
	Hydrocortisone acetate	Cream, ointment	0.5-1

Table 2: Low, medium and high daily doses of inhaled corticosteroids[6]

Adults and adolescents (12 years of age and older)			
Drug	Daily dose (mcg)		
	Low	Medium	High
Beclometasone dipropionate (CFC)	200-500	>500-1000	>1000
Beclometasone dipropionate (HFA)	100-200	>200-400	>400
Budesonide DPI	200-400	>400-800	>800
Ciclesonide (HFA)	80-160	>160-320	>320
Fluticasone furoate (DPI)	100	n.a	200
Fluticasone propionate (DPI)	100-250	>250-500	>500
Fluticasone propionate (HFA)	100-250	>250-500	>500
Mometasone furoate	110-220	>220-440	>440
Triamcinolone acetonide	400-1000	>1000-2000	>2000

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limitations may be in place

4. References:

1. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. N Engl J Med. 2016 Sep 30.
2. Eichenfield LF, Tom WL, Chamlin SL et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014; 70(1):338-51.
3. Eichenfield LF, Tom WL, Berger TG, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014; 71(1):116-32.
4. Sidbury R, Davis DM, Cohen DE, et al. Guidelines of care for the management of atopic dermatitis: Section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol. 2014 Aug;71(2):327-49.
5. Dupixent® [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. September 2024.
6. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2023. Available at http://www.ginasthma.org. Accessed June 8, 2023.
7. Castro M, Corren J, Pavord ID, et al. Dupilumab efficacy and safety in moderate-to-severe uncontrolled asthma. N 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. N Engl J Med. 2018; 378:2475-85.
9. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016;6:S22-S209.
10. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immuno. 2014;113:347-385.
11. Hamilos DL. Chronic rhinosinusitis: management. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com (Accessed on May 4, 2021.)

12. Hamilos DL, Holbrook EH. Chronic rhinosinusitis: Clinical manifestations, pathophysiology, and diagnosis. UpToDate. Waltham, MA: UpToDate Inc. https://www.uptodate.com. Accessed on November 10, 2021.
13. Dellon ES, Liacouras CA, Molina-Infante J, et al. Updated International Consensus Diagnostic Criteria for Eosinophilic Esophagitis: Proceedings of the AGREE Conference. *Gastroenterology*. 2018;155(4):1022-1033.e10.
14. Dellon ES, Gonsalves Nirmala, Hirano Ikuo, et.al. ACG Clinical Guideline: Evidenced Based Approach to the Diagnosis and Management of Esophageal Eosinophilia and Eosinophilic Esophagitis (EoE), American Journal of Gastroenterology: May 2013 - Volume 108 - Issue 5 - p 679-692.
15. Holguin F, Cardet JC, Chung KF, Diver S, Ferreira DS, Fitzpatrick A, Gaga M, Kellermeyer L, Khurana S, Knight S, McDonald VM, Morgan RL, Ortega VE, Rigau D, Subbarao P, Tonia T, Adcock IM, Bleecker ER, Brightling C, Boulet LP, Cabana M, Castro M, Chanez P, Custovic A, Djukanovic R, Frey U, Frankemölle B, Gibson P, Hamerlijnck D, Jarjour N, Konno S, Shen H, Vitary C, Bush A. Management of severe asthma: a European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2020 Jan 2;55(1):1900588. doi: 10.1183/13993003.00588-2019. PMID: 31558662

Program	Prior Authorization/Medical Necessity - Dupixent (dupilumab)
Change Control	
1/2017	New program.
5/2017	Updated background and references. Dupixent approved on 3/28/2017.
7/2017	Updated criteria to differentiate based on physician assessment of severity. Eucrisa added as required treatment in moderate severity disease. Added criteria allowing treatment if disease history required treatment with systemic immunosuppressants. Added criteria for patients previously on therapy. Added sample pack language. Removed medical record submission requirement while adding requirement for medication trial or contraindication documentation. Added corticosteroid potency table as reference.
7/2018	Annual review with no change to coverage criteria. Updated reference.
12/2018	Updated background and formatting and added criteria for new indication for moderate-to-severe asthma.
4/2019	Updated background and criteria for updated indication of adolescent atopic dermatitis. Removed criteria regarding history of systemic immunosuppressant for atopic dermatitis use as allowance for initial approval as no longer critical with market availability surpassing 2 years.
10/2019	Updated Dupixent® (dupilumab) background and criteria for new indication for CRSwNP. Updated references.
4/2020	Updated criteria for atopic dermatitis requiring failure of two topicals for all severities of atopic dermatitis
5/2020	Updated criteria for clarification without change to clinical intent
6/2020	Updated background and criteria to include new indication for moderate-to-severe atopic dermatitis in children aged 6 to 11 years. Aligned specialist requirement across indications for initial authorizations and reauthorization.
6/2021	Annual review with no change to criteria. Updated background, drug examples, and references.

12/2021	Updated background and criteria to include expanded indication of moderate to severe eosinophilic or oral corticosteroid dependent asthma to patients aged 6 years and older. Updated references.
2/2022	Removed bypass of initial authorization for patients currently on therapy with Dupixent for all indications. Updated initial authorization period to 12 months. Updated agents not to be used in combination with Dupixent for all indications. Removed age requirement from atopic dermatitis and asthma coverage criteria. Updated coverage criteria for CRSwNP. Updated references. Added footnote to support FDA labeled first line requirements.
7/2022	Added clinical criteria for eosinophilic esophagitis. Removed footnote regarding sample initiation from the asthma as this no longer applies. Updated background, state mandate, and references.
11/2022	Updated criteria to include new indication for prurigo nodularis. Updated reference.
3/2023	Updated not used in combination criteria for atopic dermatitis and prurigo nodularis.
7/2023	Updated coverage criteria for severe asthma to align with GINA & ERS/ATS guidelines. Added/updated examples of ICS-containing maintenance medications and removed requirement that peripheral blood eosinophil level must be within 6 weeks. Updated references.
3/2024	Clarified topical steroid potency in atopic dermatitis with no change to clinical intent or coverage criteria. Removed weight requirement from Eosinophilic Esophagitis criteria. Updated state mandate footnote, background and reference.
11/2024	Added criteria to include new indication for chronic obstructive pulmonary disorder. Updated background and reference.