

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 2116-5
Program	Prior Authorization/Medical Necessity
Medications	Dupixent® (dupilumab)
P&T Approval Date	1/2017, 5/2017, 7/2017, 7/2018, 12/2018
Effective Date	2/1/2019; Oxford only: 3/1/2019

1. Background:

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for treatment of adult patients 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 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.

2. Coverage Criteria:

A. Atopic Dermatitis

1. Initial Authorization

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

(1) Patient is 18 years of age or older

-AND-

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

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

i. Diagnosis of chronic atopic dermatitis that has been determined to be moderate in severity based on physician assessment

-AND-

ii. **One** of the following:

1. Disease history that has required systemic immunosuppressive therapy for control with **one** of the following: (document drug, and date of trial)

- a. Cyclosporine
- b. Azathioprine
- c. Methotrexate
- d. Mycophenolate mofetil

-OR-

2. History of failure, contraindication, or intolerance to **all** of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)

- a. Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone acetonide), Lidex (fluocinonide)]^a
- b. One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)].*^a
- c. Eucrisa (crisaborole)*

-OR-

(b) **All** of the following:

- i. Diagnosis of chronic atopic dermatitis that has been determined to be severe based on physician assessment

-AND-

ii. **One** of the following:

1. Disease history that has required systemic immunosuppressive therapy for control with **one** of the following: (document drug, and date of trial)

- a. Cyclosporine
- b. Azathioprine
- c. Methotrexate
- d. Mycophenolate mofetil

-OR-

2. History of failure, contraindication, or intolerance to **both** of the following topical therapies: (document drug, date of trial, and/or contraindication to medication)^a

- a. Medium to very-high potency topical corticosteroid [e.g., Elocon (mometasone furoate), Synalar (fluocinolone

acetonide), Lidex (fluocinonide)]

- b. One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)].*

-OR-

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

- i. Patient is currently on Dupixent therapy

-AND-

- ii. Patient has not received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Dupixent[‡]

[‡] Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay™ program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

-AND-

- (3) Patient is **not** receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

-AND-

- (4) 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 **both** of the following criteria:

- (1) Documentation of positive clinical response to Dupixent therapy

-AND-

- (2) Patient is **not** receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

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) Patient is 12 years of age or older

-AND-

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

- (a) **All** of the following

- i. Classification of asthma as uncontrolled or inadequately controlled as defined by at least **one** of the following
1. 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)
 2. Two or more bursts of systemic corticosteroids for at least 3 days each in the previous 12 months
 3. Asthma-related emergency treatment (e.g., emergency room visit, hospital admission, or unscheduled physician's office visit for nebulizer or other urgent treatment)
 4. 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])
 5. Patient is currently dependent on oral corticosteroids for the treatment of asthma

-AND-

- ii. Dupixent will be used in combination with **one** of the following:

1. **One** high dose (appropriately adjusted for age) combination inhaled corticosteroid (ICS)/long-acting beta₂ agonist (LABA) [e.g., Advair/AirDuo Resplick (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone furoate/vilanterol)]

-OR-

2. Combination therapy including **both** of the following:

- a. **One** high-dose (appropriately adjusted for age) ICS product [e.g., ciclesonide (Alvesco), mometasone furoate (Asmanex), beclomethasone dipropionate (QVAR)]

-AND-

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

-AND-

- iii. **One** of the following:

1. 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/ μ L within the past 6 weeks

-OR-

2. Patient is currently dependent on oral corticosteroids for the treatment of asthma

-OR-

- (b) **Both** of the following:

- i. Patient is currently on Dupixent therapy

-AND-

- ii. Patient has not received a manufacturer supplied sample at no cost

in prescriber office, or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay™ program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Dupixent[‡]

-AND-

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

- (a) Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenna (benralizumab)]
- (b) Anti-IgE therapy [e.g. Xolair (omalizumab)]

-AND-

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

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

[‡] Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Sanofi and Regeneron Pharmaceuticals sponsored Dupixent MyWay™ program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

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 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 controller medication

-AND-

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

- (a) Anti-interleukin-5 therapy [e.g. Nucala (mepolizumab), Cinqair (reslizumab), Fasenna (benralizumab)]
- (b) Anti-IgE therapy [e.g. Xolair (omalizumab)]

-AND-

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

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

Authorization will be issued for 12 months.

^aTried/failed alternative(s) are supported by FDA labeling

* Elidel, Protopic/tacrolimus ointment, and Eucrisa require prior authorization.

Table 1: Relative potencies of topical corticosteroids³

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	Betamethasone valerate	Cream, foam, lotion, ointment	0.1

potency	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 corticosteroids⁶

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. October 2018.
6. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2018. Available from: www.ginaasthma.org
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.

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.