UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Dupixent

Program	Prior Authorization
Medication	Dupixent (dupilumab)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	2/2017
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

1. Background:

Dupixent (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for treatment of patients aged 6 years 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 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. Dupixent is also indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

2. Coverage Criteria:

A. Atopic Dermatitis

1. Initial Authorization

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

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

-AND-

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

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

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

acetonide), Lidex (fluocinonide)]
ii. One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]
iii. Eucrisa (crisaborole)

-OR-

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

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

-AND-

ii. History of failure, contraindication, or intolerance to **both** 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)]
b. One topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)]

-OR-

(c) Patient is currently on Dupixent therapy

-AND-

(3) Patient is 6 years of age or older

-AND-

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

-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 another biologic medication [e.g., Xolair (omalizumab), Rituxan (rituximab), Enbrel (etanercept), Remicade/Inflectra (infliximab)]

-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) 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 beta$_2$ agonist (LABA) [e.g., Advair/AirDuo Respiclick (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/µL within the past 6 weeks

-OR-

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

-OR-

(b) Patient is currently on Dupixent therapy

-AND-

(4) 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)]

-AND-

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

(a) Pulmonologist
(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 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 (resilizumab), Fasenra (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.

C. Chronic Rhinosinusitis with Nasal Polyposis

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

a. **Two or more** of the following symptoms for greater than or equal to 12 weeks duration:

1. Mucopurulent discharge

2. Nasal obstruction and congestion
3. Decreased or absent sense of smell
4. Facial pressure or pain

-AND-

b. **One** of the following:

1. Evidence of inflammation on paranasal sinus examination or computed tomography (CT)
2. Evidence of purulence coming from paranasal sinuses or ostiomeatal complex

-AND-

c. The presence of nasal polyps

-AND-

ii. **One** of the following:

a. Patient has required prior sino-nasal surgery
b. Patient has required systemic corticosteroids in the previous 2 years

-AND-

iii. Patient has been unable to obtain symptom relief after trial of **all** of the following agents/classes of agents:

1. Nasal saline irrigations
2. Intranasal corticosteroids (e.g. fluticasone, mometasone, triamcinolone, etc.)
3. Antileukotriene agents (e.g. montelukast, zafirlukast, zileuton)

-OR-

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

i. Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

-AND-

ii. Patient is currently on Dupixent therapy

-AND-

(3) Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

-AND-

(4) Patient is **not** receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

-AND-

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

(a) Otolaryngologist
(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 will continue to receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

-AND-

(3) Patient is **not** receiving Dupixent in combination with another biologic medication [e.g., Xolair (omalizumab), Nucala (mepolizumab), Cinqair (resilizumab), Fasenra (benralizumab)]

-AND-

(4) Prescribed by **one** of the following:
(a) Otolaryngologist
(b) Allergist
(c) Immunologist

Authorization will be issued for 12 months.

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
	tridifloronide	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.May 2020.
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.
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 June 27, 2019.)

Program	Prior Authorization -Dupixent (dupilumab)
Change Control	
2/2017	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. Removed medical record submission requirement while adding requirement for medication trial or contraindication documentation. Added corticosteroid potency table as a reference.
7/2018	Annual review with no change to coverage criteria. Updated references.
12/2018	Added criteria for new indication of moderate to severe asthma. Updated background and references.
4/2019	Updated background and criteria for expanded atopic dermatitis indication. 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. Updated references.
8/2019	Updated background and criteria to include new indication for CRSwNP. Updated references.
6/2020	Updated background and criteria to include new indication for moderate-to-severe atopic dermatitis in children aged 6 years of age and older. Aligned specialist requirement across indications for initial authorizations and reauthorizations. Added Additional Clinical Programs section.