UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3099-9
Program	Step Therapy
Medications	Dupixent® (dupilumab)
P&T Approval Date	7/2017, 7/2018, 12/2018, 4/2019, 11/2019, 4/2020, 5/2020, 6/2020
Effective Date	9/1/2020; Oxford only: N/A

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try two classes of topical therapies for moderate-to-severe atopic dermatitis before providing coverage for Dupixent® (dupilumab). For patients with moderate-to-severe asthma, this program requires members to be on a maintenance controller medication before receiving add-on maintenance Dupixent therapy. For patients with chronic rhinosinusitis with nasal polyposis, this program requires members to try two of the following treatment classes: intranasal corticosteroids, nasal saline irrigations and antileukotriene agents before receiving add-on maintenance Dupixent therapy.

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).

Members currently on Dupixent therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. <u>Atopic Dermatitis</u>

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

a. Diagnosis of moderate-to-severe chronic atopic dermatitis

-AND-

b. **<u>One</u>** of the following:

(1) History of failure, contraindication, or intolerance to **two** of the following therapeutic classes of 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) Topical calcineurin inhibitor [e.g., Elidel (pimecrolimus), Protopic (tacrolimus)].*
(c) Eucrisa (crisaborole)*

-OR-

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

(a) Patient is currently on Dupixent therapy

-AND-

(b) Patient has **not** received 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™ (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.

Authorization will be issued for 12 months.

B. Asthma

1. Dupixent will be approved based on **both** of the following criteria:

a. Diagnosis of moderate-to-severe asthma

-AND-

b. **One** of the following:

(1) Dupixent will be used as in combination with maintenance controller medications [e.g. combination inhaled corticosteroid (ICS)/long-acting

beta$_2$ agonist (LABA), ICS, LABA]

-OR-

(2) **Both** of the following

(a) Patient is currently on Dupixent therapy

-AND-

(b) Patient has **not** received 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™ (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.

Authorization will be issued for 12 months.

C. Chronic Rhinosinusitis with Nasal Polyposis

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

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

-AND-

b. **One** of the following:

(1) Patient has been unable to obtain symptom relief after trial of **two** of the following classes of agents:

(a) Nasal saline irrigations
(b) Intranasal corticosteroids (e.g. fluticasone, mometasone, triamcinolone, etc.)
(c) Antileukotriene agents (e.g. montelukast, zafirlukast, zileuton)

-OR-

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

(a) Patient is currently on Dupixent therapy

-AND-

(b) Patient has **not** received 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™ (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-

c. Patient will receive Dupixent as add-on maintenance therapy in combination with intranasal corticosteroids

Authorization will be issued for 12 months.

D. Other Diagnoses

1. Dupixent will be approved

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.

* Elidel, Protopic/tacrolimus 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

3. Additional Clinical Rules:

- 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
- Medical Necessity and/or Notification may be in place.
- Supply limits may be in place.

4. References:

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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. Orlandi RR, Kingdom TT, Hwang PH, et al. International consensus statement on allergy and rhinology: rhinosinusitis. Int Forum Allergy Rhinol. 2016;6:S22-S209.
9. 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.
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Program	Step Therapy - Dupixent (dupilumab)
Change Control	
7/2017	New program.
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. Updated references.
4/2019	Updated background with updated indication of adolescent atopic dermatitis.
11/2019	Updated Dupixent® (dupilumab) background and criteria for new indication for CRSwNP. Updated references.
12/2019	Administrative change to correct numbering.
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
6/2020	Updated background to include new indication for moderate-to-severe atopic dermatitis in children aged 6 to 11 years. Updated criteria for clarification without change to clinical intent