UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2018 P 1207-4
Program	Prior Authorization/Notification
Medications	Dupixent® (dupilumab)
P&T Approval Date	1/2017, 5/2017, 5/2018, 12/2018
Effective Date	2/1/2019; Oxford only: N/A

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) Diagnosis of moderate to severe chronic atopic dermatitis

-AND-

(2) Patient is 18 years of age or older

-AND-

(3) History of failure, contraindication, or intolerance to **both** of the following topical therapies:
   (a) One medium potency 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)]*.

Authorization will be issued for 6 months.

2. Reauthorization

a. **Dupixent** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Dupixent therapy

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) Dupixent will be used in combination with maintenance controller medications [e.g. combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA), ICS, LABA]

-AND-

(3) Patient is 12 years of age or older

-AND-

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

(a) Patient has an eosinophilic phenotype

-OR-

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

(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)]

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) Dupixent is being used in combination with maintenance controller medications [e.g. combination inhaled corticosteroid (ICS)/long-acting beta$_2$ agonist (LABA), ICS, LABA]

-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)]

Authorization will be issued for 12 months.

* Elidel and Protopic require prior authorization.

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.
- Medical Necessity 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, 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.
3. Dupixent® [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. October 2018.
4. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2018. Available from: www.ginaasthma.org

Program	Prior Authorization/Notification - Dupixent (dupilumab)
Change Control	
1/2017	New program.
5/2017	Updated background and references. Dupixent approved on 3/28/2017.
5/2018	Annual review. No changes to criteria.
12/2018	Updated background and formatting and added criteria for new indication for moderate-to severe asthma.