UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Dupixent

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| Program | Prior Authorization |
| Medication | Dupixent (dupilumab) |
| Issue Date | 2/2017 |
| Pharmacy and Therapeutics Approval Date | 7/2017 |
| Effective Date | 9/2017 |

## 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.

## 2. Coverage Criteria:

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

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

a. Patient is 18 years of age or older

**-AND-**

b. One of the following:

(1) **<u>All</u>** of the following:

(a) Diagnosis of chronic atopic dermatitis that has been determined to be moderate in severity based on physician assessment

**-AND-**

(b) **<u>One</u>** of the following:

i. Disease history that has required systemic immunosuppressive therapy for control with **<u>one</u>** of the following: (document drug, and date or trial)

1. Cyclosporine
2. Azathioprine
3. Methotrexate

4. Mycophenolate mofetil

**-OR-**

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

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

**-OR-**

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

(a) Diagnosis of chronic atopic dermatitis that has been determined to be severe based on physician assessment

**-AND-**

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

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

1. Cyclosporine
2. Azathioprine
3. Methotrexate
4. Mycophenolate mofetil

**-OR-**

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

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

**-OR-**

(3) Patient is currently on Dupixent therapy

**-AND-**

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

**-AND-**

d. Prescribed by **one** of the following:

(1) Dermatologist
(2) Allergist
(3) Immunologist

**Authorization will be issued for 6 months.**

**B. Reauthorization**

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

a. Documentation of positive clinical response to Dupixent therapy

**-AND-**

b. 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.**

* 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 | Amcinonide | Cream, lotion, ointment | 0.1 |

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| Potency | 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. 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. March 2017.

| 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. |