UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1207-14
Program	Prior Authorization/Notification
Medications	Dupixent® (dupilumab)
P&T Approval Date	1/2017, 5/2017, 5/2018, 12/2018, 4/2019, 8/2019, 6/2020, 6/2021, 12/2021, 7/2022, 11/2022, 3/2023, 7/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Dupixent® (dupilumab) is an interleukin-4 receptor alpha antagonist indicated for treatment of patients aged 6 months 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 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma, as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP), for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE), and for adult patients with prurigo nodularis (PN).

Limitation of Use:

Dupixent is not for the relief of acute bronchospasm or status asthmaticus.

2. Coverage Criteria[a]:

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) History of failure, contraindication, or intolerance to topical therapies

-AND-

3) Patient is not receiving Dupixent in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

Authorization will be issued for 12 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 **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

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 therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-AND-

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

(a) Patient has an eosinophilic phenotype

-OR-

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

-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)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire

(tezepelumab)]

Authorization will be issued for 12 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 therapy [e.g., Advair/AirDuo (fluticasone/salmeterol), Breo Ellipta (fluticasone furoate/vilanterol), Symbicort (budesonide/ formoterol), Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol)].

-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)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

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) Diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP)

-AND-

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

-AND-

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

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire

(tezepelumab)]

Authorization will be issued for 12 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 **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 12 months.

D. Eosinophilic Esophagitis

1. **Initial Authorization**

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

(1) Diagnosis of eosinophilic esophagitis

-AND-

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

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

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 **any** of the following:

(a) Anti-interleukin-5 therapy [e.g., Cinqair (resilizumab), Fasenra (benralizumab), Nucala (mepolizumab)]
(b) Anti-IgE therapy [e.g., Xolair (omalizumab)]
(c) Thymic stromal lymphopoietin (TSLP) inhibitor [e.g., Tezspire (tezepelumab)]

Authorization will be issued for 6 months.

E. Prurigo Nodularis

1. **Initial Authorization**

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

(1) Diagnosis of prurigo nodularis

-AND-

(2) Patient is not receiving Dupixent in combination with **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

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 **either** of the following:

(a) Biologic immunomodulator [e.g., Adbry (tralokinumab-ldrm)]
(b) Janus kinase inhibitor [e.g., Rinvoq (upadacitinib), Xeljanz/XR (tofacitinib), Opzelura (topical ruxolitinib), Cibinqo (abrocitinib)]

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.

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. Dupixent® [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc. January 2024.

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.
4/2019	Updated background and criteria for updated indication of adolescent atopic dermatitis.
8/2019	Updated background and criteria for updated indication of CRSwNP.
6/2020	Updated background and criteria to include new indication for moderate-to-severe atopic dermatitis in children aged 6 to 11 years. Updated initial authorization to 12 months.
6/2021	Updated background and examples with no change to coverage criteria. Updated references.
12/2021	Updated background and criteria to include expanded indication of moderate to severe eosinophilic or oral corticosteroid dependent asthma to patients aged 6 years and older. Updated references.
7/2022	Updated criteria to include new indication for eosinophilic esophagitis. Updated not used in combination examples for all indications. Updated atopic dermatitis criteria and background to reflect patients older than 6 months. Added state mandate footnote. Updated background and reference.
11/2022	Updated criteria to include new indication for prurigo nodularis. Updated reference.
3/2023	Updated not used in combination criteria for atopic dermatitis and prurigo nodularis.
7/2023	Within the Asthma section, updated examples of maintenance therapy. Throughout program, removed age requirements.
3/2024	Removed weight requirement from Eosinophilic Esophagitis criteria. Updated background and reference.