

## **Clinical Policy: Dupilumab (Dupixent)**

Reference Number: CP.PHAR.336

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Line of Business: Commercial, HIM, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Dupilumab (Dupixent<sup>®</sup>) is an interleukin-4 receptor alpha antagonist.

### **FDA Approved Indication(s)**

Dupixent is indicated:

- For the 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.
- 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 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

Limitation(s) of use: Not for the relief of acute bronchospasm or status asthmaticus

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with Centene Corporation<sup>®</sup> that Dupixent is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. Atopic Dermatitis** (must meet all):

1. Diagnosis of atopic dermatitis affecting one of the following (a or b):
  - a. At least 10% of the member's body surface area (BSA);
  - b. Hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas;
2. Prescribed by or in consultation with a dermatologist or allergist;
3. Age  $\geq$  6 months;
4. Failure of both of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced:
  - a. Two formulary medium to very high potency topical corticosteroids of different molecular identities, each used for  $\geq$  2 weeks;

- b. One non-steroidal topical therapy\* used for  $\geq 4$  weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa<sup>®</sup>;  
*\*These agents may require prior authorization*
5. If member is age  $> 2$  years, failure of one of the following systemic agents used for  $\geq 3$  months, unless clinically significant adverse effects are experienced or all are contraindicated: azathioprine, methotrexate, mycophenolate mofetil, or cyclosporine;
6. Dupixent is not prescribed concurrently with Cinqair<sup>®</sup>, Fasenna<sup>®</sup>, Nucala<sup>®</sup>, Tezspire<sup>™</sup>, or Xolair<sup>®</sup>;
7. Dose does not exceed one of the following (a, b, or c):
  - a. Age 6 months to 5 years and weight 5 to  $< 15$  kg: 200 mg every 4 weeks;
  - b. Age 6 months to 5 years and weight 15 to  $< 30$  kg: 300 mg every 4 weeks;
  - c. Age  $\geq 6$  years and the following:
    - i. Initial (one-time) dose:
      - 1) Age  $\geq 18$  years, weight  $\geq 60$  kg, or age 6-17 years and weight 15 to  $< 30$  kg: 600 mg;
      - 2) Age 6-17 years and weight 30 to  $< 60$  kg: 400 mg;
    - ii. Maintenance dose:
      - 1) Age  $\geq 18$  years or weight  $\geq 60$  kg: 300 mg every other week;
      - 2) Age 6-17 years and weight 30 to  $< 60$  kg: 200 mg every other week;
      - 3) Age 6-17 years and weight 15 to  $< 30$  kg: 300 mg every 4 weeks.

**Approval duration: 6 months**

**B. Asthma (must meet all):**

1. Diagnosis of asthma and one of the following (a or b):
  - a. Absolute blood eosinophil count  $\geq 150$  cells/mcL within the past 3 months;
  - b. Currently receiving maintenance treatment with systemic glucocorticoids and has received treatment for at least 4 weeks;
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
3. Age  $\geq 6$  years;
4. Member has experienced  $\geq 2$  exacerbations within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid [ICS] plus either a long-acting beta<sub>2</sub> agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance):
  - a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid);
  - b. Urgent care visit or hospital admission;
  - c. Intubation;
5. Dupixent is prescribed concurrently with an ICS plus either a LABA or LTRA;
6. Dupixent is not prescribed concurrently with Cinqair, Fasenna, Nucala, Tezspire, or Xolair;
7. Dose does not exceed the following:
  - a. Initial (one-time) dose for age  $\geq 12$  years: 600 mg;
  - b. Maintenance dose:
    - i. Age  $\geq 12$  years: 300 mg every other week;
    - ii. Age 6-11 years and weight  $\geq 30$  kg: 200 mg every other week;
    - iii. Age 6-11 years and weight 15 to  $< 30$  kg: 300 mg every 4 weeks.

**Approval duration: 6 months**

**C. Chronic Rhinosinusitis with Nasal Polyposis (must meet all):**

1. Diagnosis of CRSwNP with documentation of all of the following (a, b, and c):
  - a. Presence of nasal polyps;
  - b. Disease is bilateral;
  - c. Member has experienced signs and symptoms (e.g., nasal congestion/blockage/obstruction, loss of smell, rhinorrhea) for  $\geq 12$  weeks;
2. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist;
3. Age  $\geq 18$  years;
4. Member has required the use of systemic corticosteroids for symptom control within the last 2 years, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B for examples*);
5. Failure of maintenance therapy with at least three intranasal corticosteroids, one of which must be Xhance™, each used for  $\geq 4$  weeks, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B for examples*);
6. Dupixent is prescribed concurrently with an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B for examples*);
7. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
8. Dose does not exceed 300 mg every other week.

**Approval duration: 6 months**

**D. Eosinophilic Esophagitis (must meet all):**

1. Diagnosis of EoE confirmed by  $\geq 15$  intraepithelial eosinophils per high-power field (eos/hpf) on endoscopic biopsy;
2. Prescribed by or in consultation with an allergist, immunologist, or gastroenterologist;
3. Age  $\geq 12$  years;
4. Weight  $\geq 40$  kg;
5. Member does not have hypereosinophilic syndrome or eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome);
6. Failure of one of the following (a or b), unless clinically significant adverse effects are experienced or both are contraindicated:
  - a. Proton pump inhibitor (*see Appendix B for examples*);
  - b. Corticosteroid (*see Appendix B for examples*);
7. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
8. Dose does not exceed 300 mg every week.

**Approval duration: 6 months**

**E. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):

- a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Atopic Dermatitis (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;
3. Dupixent is not prescribed concurrently with Cinqair, Fasenna, Nucala, Tezspire, or Xolair;
4. If request is for a dose increase, new dose does not exceed:
  - a. Age  $\geq$  18 years or weight  $\geq$  60 kg: 300 mg every other week;
  - b. Age 6-17 years and weight 30 to  $<$  60 kg: 200 mg every other week;
  - c. Age 6-17 years and weight 15 to  $<$  30 kg: 300 mg every 4 weeks;
  - d. Age 6 months to 5 years and weight 5 to  $<$  15 kg: 200 mg every 4 weeks;
  - e. Age 6 months to 5 years and weight 15 to  $<$  30 kg: 300 mg every 4 weeks.

#### Approval duration:

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member’s renewal date, whichever is longer

### B. Asthma (must meet all):

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Demonstrated adherence to asthma controller therapy (an ICS plus either a LABA or LTRA) as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months

- (i.e., member has received asthma controller therapy for at least 5 of the last 6 months);
3. Member is responding positively to therapy (examples may include but are not limited to: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, reduction in the use of rescue therapy);
  4. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
  5. If request is for a dose increase, new dose does not exceed:
    - a. Age  $\geq$  12 years: 300 mg every other week;
    - b. Age 6-11 years and weight  $\geq$  30 kg: 200 mg every other week;
    - c. Age 6-11 years and weight 15 to  $<$  30 kg: 300 mg every 4 weeks.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member’s renewal date, whichever is longer

**C. Chronic Rhinosinusitis with Nasal Polyposis (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Demonstrated adherence to an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;
3. Member is responding positively to therapy (examples may include but are not limited to: reduced nasal polyp size, reduced need for systemic corticosteroids, improved sense of smell, improved quality of life);
4. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
5. If request is for a dose increase, new dose does not exceed 300 mg every other week.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member’s renewal date, whichever is longer

**D. Eosinophilic Esophagitis (must meet all):**

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy (examples may include but are not limited to: reduced eos/hpf count, improvement in dysphagia symptoms);
3. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;

4. If request is for a dose increase, new dose does not exceed 300 mg every week.

**Approval duration:**

**Medicaid/HIM** – 12 months

**Commercial** – 6 months or to the member’s renewal date, whichever is longer

**E. Other diagnoses/indications (must meet 1 or 2):**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents;
- B. Acute bronchospasm or status asthmaticus.

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

CRSwNP: chronic rhinosinusitis with nasal polyposis  
EoE: eosinophilic esophagitis  
eos/hpf: eosinophils per high-power field  
FDA: Food and Drug Administration

GINA: Global Initiative for Asthma  
ICS: inhaled corticosteroid  
LABA: long-acting beta<sub>2</sub> agonist  
LTRA: leukotriene modifier  
PDC: proportion of days covered

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>ATOPIC DERMATITIS</b>		
<b>Very High Potency Topical Corticosteroids</b>		
augmented betamethasone 0.05% (Diprolene <sup>®</sup> AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
clobetasol propionate 0.05% (Temovate <sup>®</sup> ) cream, ointment, gel, solution		
diflorasone diacetate 0.05% (Maxiflor <sup>®</sup> , Psorcon E <sup>®</sup> ) cream, ointment		
fluocinonide 0.1% cream		
flurandrenolide 4 mcg/cm <sup>2</sup> tape		
halobetasol propionate 0.05% (Ultravate <sup>®</sup> ) cream, ointment		
<b>High Potency Topical Corticosteroids</b>		
amcinonide 0.1% ointment, lotion	Apply topically to the affected area(s) BID	Varies
augmented betamethasone 0.05% (Diprolene <sup>®</sup> AF) cream, ointment, gel, lotion		
betamethasone valerate 0.1%, 0.12% (Luxiq <sup>®</sup> ) ointment, foam		
clobetasol propionate 0.025% (Impoyz <sup>®</sup> ) cream		
diflorasone 0.05% (Florone <sup>®</sup> , Florone E <sup>®</sup> , Maxiflor <sup>®</sup> , Psorcon E <sup>®</sup> ) cream		
fluocinonide acetone 0.05% (Lidex <sup>®</sup> , Lidex E <sup>®</sup> ) cream, ointment, gel, solution		
fluticasone propionate 0.005% cream, ointment		
halcinonide 0.1% cream, ointment, solution (Halog <sup>®</sup> )		
halobetasol propionate 0.01% lotion (Bryhali <sup>®</sup> )		
mometasone furoate 0.1% ointment		
triamcinolone acetone 0.5% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Medium Potency Topical Corticosteroids</b>		
clocortolone pivalate 0.1% cream	Apply topically to the affected area(s) BID	Varies
desoximetasone 0.05%, 0.25% (Topicort <sup>®</sup> ) cream, ointment, gel, spray		
fluocinolone acetonide 0.025% (Synalar <sup>®</sup> ) cream, ointment		
flurandrenolide 0.05% lotion, ointment (Cordran <sup>®</sup> )		
hydrocortisone valerate 0.2% cream		
mometasone 0.1% (Elocon <sup>®</sup> ) cream, ointment, lotion		
triamcinolone acetonide 0.025%, 0.1% (Aristocort <sup>®</sup> , Kenalog <sup>®</sup> ) cream, ointment		
<b>Other Classes of Agents</b>		
Protopic <sup>®</sup> (tacrolimus), Elidel <sup>®</sup> (pimecrolimus)	Children ≥ 2 years and adults: Apply a thin layer topically to affected skin BID. Treatment should be discontinued if resolution of disease occurs.	Varies
Eucrisa <sup>®</sup> (crisaborole)	Apply to the affected areas BID	Varies
cyclosporine	3-6 mg/kg/day PO BID	300 mg/day
azathioprine	1-3 mg/kg/day PO QD	Weight-based
methotrexate	7.5-25 mg/wk PO once weekly	25 mg/week
mycophenolate mofetil	1-1.5 g PO BID	3 g/day
<b>ASTHMA</b>		
<b>ICS (medium – high dose)</b>		
Qvar <sup>®</sup> (beclomethasone)	> 200 mcg/day 40 mcg, 80 mcg per actuation 1-4 actuations BID	4 actuations BID
budesonide (Pulmicort <sup>®</sup> )	> 400 mcg/day 90 mcg, 180 mcg per actuation 2-4 actuations BID	2 actuations BID
Alvesco <sup>®</sup> (ciclesonide)	> 160 mcg/day 80 mcg, 160 mcg per actuation 1-2 actuations BID	2 actuations BID
Aerospan <sup>®</sup> (flunisolide)	> 320 mcg/day 80 mcg per actuation 2-4 actuations BID	2 actuations BID
Flovent <sup>®</sup> (fluticasone propionate)	> 250 mcg/day 44-250 mcg per actuation	2 actuations BID



Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	2-4 actuations BID	
Arnuity Ellipta <sup>®</sup> (fluticasone furoate)	200 mcg/day 100 mcg, 200 mcg per actuation 1 actuation QD	1 actuation QD
Asmanex <sup>®</sup> (mometasone)	>220 mcg/day HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation 1-2 actuations QD to BID	2 inhalations BID
<b>LABA</b>		
Serevent <sup>®</sup> (salmeterol)	50 mcg per dose 1 inhalation BID	1 inhalation BID
<b>Combination products (ICS + LABA)</b>		
Dulera <sup>®</sup> (mometasone/formoterol)	100/5 mcg, 200/5 mcg per actuation 2 actuations BID	4 actuations per day
Breo Ellipta <sup>®</sup> (fluticasone/vilanterol)	100/25 mcg, 200/25 mcg per actuation 1 actuation QD	1 actuation QD
Advair <sup>®</sup> (fluticasone/ salmeterol)	Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation 1 actuation BID	1 actuation BID
fluticasone/salmeterol (Airduo RespiClick <sup>®</sup> )	55/13 mcg, 113/14 mcg, 232/14 mcg per actuation 1 actuation BID	1 actuation BID
Symbicort <sup>®</sup> (budesonide/formoterol)	80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation 2 actuations BID	2 actuations BID
<b>LTRA</b>		
montelukast (Singulair <sup>®</sup> )	4 to 10 mg PO QD	10 mg per day
zafirlukast (Accolate <sup>®</sup> )	10 to 20 mg PO BID	40 mg per day
zileuton ER (Zyflo <sup>®</sup> CR)	1,200 mg PO BID	2,400 mg per day
Zyflo <sup>®</sup> (zileuton)	600 mg PO QID	2,400 mg per day
<b>Oral corticosteroids</b>		
dexamethasone (Decadron <sup>®</sup> )	0.75 to 9 mg/day PO in 2 to 4 divided doses	Varies
methylprednisolone (Medrol <sup>®</sup> )	40 to 80 mg PO in 1 to 2 divided doses	Varies
prednisolone (Millipred <sup>®</sup> , Orapred ODT <sup>®</sup> )	40 to 80 mg PO in 1 to 2 divided doses	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
prednisone (Deltasone <sup>®</sup> )	40 to 80 mg PO in 1 to 2 divided doses	Varies
<b>CRSwNP</b>		
<b>Intranasal corticosteroids</b>		
beclomethasone (Beconase AQ <sup>®</sup> , Qnasl <sup>®</sup> )	1-2 sprays IN BID	2 sprays/nostril BID
budesonide (Rhinocort <sup>®</sup> Aqua, Rhinocort <sup>®</sup> )	128 mcg IN QD or 200 mcg IN BID	1-2 inhalations/nostril/day
flunisolide	2 sprays IN BID	2 sprays/nostril TID
fluticasone propionate (Flonase <sup>®</sup> )	1-2 sprays IN BID	2 sprays/nostril BID
mometasone (Nasonex <sup>®</sup> )	2 sprays IN BID	2 sprays/nostril BID
Omnanis <sup>®</sup> , Zetonna <sup>®</sup> (ciclesonide)	Omnanis: 2 sprays IN QD Zetonna: 1 spray IN QD	Omnanis: 2 sprays/ nostril/day Zetonna: 2 sprays/ nostril/day
triamcinolone (Nasacort <sup>®</sup> )	2 sprays IN QD	2 sprays/ nostril/day
Xhance <sup>™</sup> (fluticasone propionate)	1 to 2 sprays (93 mcg/spray) to nostril IN BID	744 mcg/day
<b>Oral corticosteroids</b>		
dexamethasone (Decadron <sup>®</sup> )	0.75 to 9 mg/day PO in 2 to 4 divided doses	Varies
methylprednisolone (Medrol <sup>®</sup> )	4 to 48 mg PO in 1 to 2 divided doses	Varies
prednisolone (Millipred <sup>®</sup> , Orapred ODT <sup>®</sup> )	5 to 60 mg PO in 1 to 2 divided doses	Varies
prednisone (Deltasone <sup>®</sup> )	5 to 60 mg PO in 1 to 2 divided doses	Varies
<b>EoE</b>		
Corticosteroids: examples – <ul style="list-style-type: none"> <li>• <u>Topical</u>: <ul style="list-style-type: none"> <li>○ Budesonide administered as an oral viscous slurry of budesonide inhalation suspension [Pulmicort Respules<sup>®</sup>] with sucralose or similar carrier vehicle</li> <li>○ Fluticasone propionate administered using a metered dose inhaler</li> </ul> </li> <li>• <u>Oral</u>: <ul style="list-style-type: none"> <li>○ Prednisone</li> </ul> </li> </ul>	Varies	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Proton pump inhibitors (e.g., omeprazole, esomeprazole, lansoprazole, rabeprazole, pantoprazole)	Varies	Varies

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): known hypersensitivity to Dupixent or any of its excipients
- Boxed warning(s): none reported

*Appendix D: General Information*

- Atopic dermatitis:
  - The Phase III pivotal studies (SOLO 1 and SOLO 2) of Dupixent showed no significant difference in clinical outcomes between dosing of Dupixent every week and every other week for the treatment of atopic dermatitis.
- Asthma
  - During clinical trials (LIBERTY ASTHMA QUEST), among patients with a baseline blood eosinophil count of < 150 per cubic millimeter, the exacerbation rate was similar with dupilumab and with placebo: 0.47 (95% CI, 0.36 to 0.62) with lower-dose dupilumab and 0.51 (95% CI, 0.35 to 0.76) with matched placebo, and 0.74 (95% CI, 0.58 to 0.95) with higher-dose dupilumab and 0.64 (95% CI, 0.44 to 0.93) with matched placebo.
  - The Global Initiative for Asthma (GINA) guidelines for difficult-to-treat and severe asthma recommend Dupixent be considered as adjunct therapy for patients 12 years of age and older with exacerbations or poor symptom control despite taking at least high dose ICS/LABA and who have eosinophilic biomarkers or need maintenance oral corticosteroids. Dupixent may also be considered if the patient is uncontrolled on Step 4 treatment (medium dose ICS/LABA).
  - Patients could potentially meet asthma criteria for both Xolair and Dupixent, though there is insufficient data to support the combination use of multiple asthma biologics. The combination has not been studied. Approximately 30% of patients in the Nucala MENSA study also were candidates for therapy with Xolair.
  - Lab results for blood eosinophil counts can be converted into cells/mcL using the following unit conversion calculator: <https://www.fasenrahcp.com/m/fasenra-eosinophil-calculator.html>
  - PDC is a measure of adherence. PDC is calculated as the sum of days covered in a time frame divided by the number of days in the time frame. To achieve a PDC of 0.8, a member must have received their asthma controller therapy for 144 days out of the last 180 days, or approximately 5 months of the last 6 months.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate-to-severe atopic dermatitis	<p><i>Adults:</i> Initial dose of 600 mg SC followed by 300 mg SC every other week</p> <p><i>Adolescents 6-17 years of age:</i></p> <ul style="list-style-type: none"> <li>• Body weight 15 to &lt; 30 kg: Initial dose of 600 mg SC followed by 300 mg SC every 4 weeks</li> <li>• Body weight 30 kg to &lt; 60 kg: Initial dose of 400 mg SC followed by 200 mg SC every other week</li> <li>• Body weight <math>\geq</math> 60 kg: Initial dose of 600 mg SC followed by 300 mg SC every other week</li> </ul> <p><i>Pediatrics 6 months - 5 years of age:</i></p> <ul style="list-style-type: none"> <li>• Body weight 5 to &lt; 15 kg: 200 mg SC every 4 weeks</li> <li>• Body weight 15 to &lt; 30 kg: 300 mg SC every 4 weeks</li> </ul>	See regimen
Moderate-to-severe asthma	<p><i>Adults and adolescents (12 years and older):</i> Initial dose of 400 mg SC followed by 200 mg SC every other week; or Initial dose of 600 mg SC followed by 300 mg SC every other week</p> <p>For patients requiring concomitant oral corticosteroids or with co-morbid moderate-to-severe atopic dermatitis for which Dupixent is indicated, start with an initial dose of 600 mg SC followed by 300 mg SC every other week</p> <p><i>Adolescents 6-11 years of age:</i></p> <ul style="list-style-type: none"> <li>• Body weight 15 to &lt; 30 kg: Initial dose and subsequent dose of 100 mg SC every other week or 300 mg every four weeks</li> <li>• Body weight <math>\geq</math> 30 kg: Initial dose and subsequent dose of 200 mg SC every other week</li> </ul> <p>For pediatric patients (6 to 11 years old) with asthma and co-morbid moderate-to-severe atopic dermatitis, follow the recommended adolescent atopic dermatitis dosing, which includes an initial loading dose</p>	See regimen

Indication	Dosing Regimen	Maximum Dose
CRSwNP	300 mg SC every other week	300 mg every other week
EoE	300 mg SC every week	300 mg/week

#### VI. Product Availability\*

- Pre-filled syringes with needle shield for injection: 100 mg/0.67 mL, 200 mg/1.14 mL, 300 mg/2 mL
- Pre-filled pen: 200 mg/1.14 mL, 300 mg/2 mL

*\*The pre-filled pen is only for use in adults and adolescents aged 12 years and older. In adolescents 12 years of age and older, it is recommended that Dupixent be given by or under the supervision of an adult. Dupixent pre-filled syringe should be given by a caregiver in children 6 months to 11 years of age.*

#### VII. References

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**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399; J3590	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: policies combined for HIM, Medicaid and commercial; no significant changes; references were reviewed and updated.	11.15.17	02.18
1Q 2019 annual review: criteria added for new FDA indication: moderate-to-severe asthma; references reviewed and updated.	12.04.18	02.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Increased initial approval duration of AD from 16 weeks to 6 months; clarified positive response to therapy examples.	02.19.19	05.19
Updated atopic dermatitis with new FDA-approved age extension to patients 12 years of age and older; references reviewed and updated.	03.21.19	
Criteria added for new FDA indication: CRSwNP; added allergists as potential prescribers for atopic dermatitis; references reviewed and updated.	08.06.19	11.19
1Q 2020 annual review: added requirement that Dupixent is not prescribed concurrently with other biologic therapies for asthma to all other indications and on re-authorization; references reviewed and updated.	11.07.19	02.20
For CRSwNP revised redirection from two to three intranasal corticosteroids per SDC and prior clinical guidance.	01.15.20	
Atopic dermatitis: added requirement for at least 10% BSA involvement, unless hands, feet, face, neck, scalp, genitals/groin, and/or intertriginous areas are affected; modified age restriction from 12 years to 6 years and revised max dosing requirements per updated FDA labeling; removed corticosteroids as a systemic agent trial option per ADA guidelines; specified that systemic agents should be tried for at least 3 months; added new pre-filled pen formulation.	06.22.20	08.20
1Q 2021 annual review: no significant changes; references to HIM.PHAR.21 revised to HIM.PA.154; references reviewed and updated.	10.26.20	02.21
For nasal polyps, specified that one of the tried intranasal steroids must be Xhance and modified trial duration from 8 weeks to 4 weeks per 2021 consensus panel treatment algorithm; RT4: added newly approved 200 mg/1.14 mL pre-filled pen.	06.16.21	08.21
1Q 2022 annual review: RT4: expanded age to 6+ years old for asthma and added new 100 mg prefilled syringe formulation; for asthma continuation criteria, defined adherence as PDC of 0.8; added Legacy WellCare line of business (WCG.CP.PHAR.336 to retire); added “Acute bronchospasm or status asthmaticus” to section III as indications for which coverage is not authorized per PI; references reviewed and updated.	11.16.21	02.22
RT4: criteria added for new FDA indication of EoE and pediatric age expansion in AD; for AD redirection to oral immunosuppressants, added minimum age of 2 years; for all indications, added Tezspire as an agent with which Dupixent should not be used concurrently.	07.13.22	08.22
Template changes applied to other diagnoses/indications and continued therapy section.	09.21.22	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
For AD indication: clarified that topical corticosteroids requirement is for corticosteroids of different molecular identities and expanded examples of medium to very high potency topical corticosteroids in Appendix B; removed low potency topical corticosteroids from Appendix B.	11.04.22	

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.



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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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