# Clinical Policy: Dupilumab (Dupixent)

Reference Number: GA.PMN.32
Effective Date: 7/24
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Line of Business: Medicaid

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
Dupilumab (Dupixent®) is an interleukin-4 receptor alpha antagonist.

**FDA Approved Indication(s)**
Dupixent is indicated:

- For the treatment of adult and pediatric 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 of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- As an add-on maintenance treatment in adult and pediatric patients aged 12 and older 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).
- For the treatment of adult patients with prurigo nodularis (PN).
- As an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
- For the treatment of adult and pediatric patients aged 12 years and older with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
- For the treatment of adult patients with bullous pemphigoid (BP).
- For the treatment of adult and pediatric patients aged 6 years and older with allergic fungal rhinosinusitis (AFRS) who have a history of sino-nasal surgery.

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® 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) as evidenced by chart notes:
   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 ≥ 6 months;
4. Failure of both of the following (a and b), unless contraindicated or clinically significant adverse effects are experienced as evidenced by prescription claims unless member is new to plan (<3 months eligibility):
   a. One formulary medium to very high potency topical corticosteroid used for ≥ 2 weeks;
   b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment, pimecrolimus 1% cream) or Eucrisa®;
   **These agents may require prior authorization*
5. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry™, Cinqair®, Fasenra®, Nucala®, Tezspire™, Xolair®) or a Janus kinase (JAK) inhibitor (e.g., Olumiant®, Rinvoq®, Cibinqo®, Opzelura™);
6. 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 ≥ 6 years and the following:
      i. Initial (one-time) dose:
         1) Age ≥ 18 years, weight ≥ 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 ≥ 18 years or weight ≥ 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: 12 months**

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

1. Diagnosis of asthma and one of the following (a or b):
   a. Absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months as evidenced by chart notes;
   b. Currently receiving maintenance treatment with systemic glucocorticoids and has received treatment for at least 4 weeks as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
3. Age ≥ 6 years;
4. Member has experienced ≥ 2 exacerbations within the last 12 months, requiring one of the following (a or b), despite adherent use of controller therapy (i.e., medium- to

high-dose inhaled corticosteroid [ICS] plus either a long-acting beta$_2$ agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance):
   a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid) as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
   b. Urgent care/emergency room (ER) visit or hospital admission as evidenced by chart notes;
5. Dupixent is prescribed concurrently with an ICS plus either a LABA or LTRA;
6. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
7. Dose does not exceed the following:
   a. Initial (one-time) dose for age ≥ 12 years: 600 mg;
   b. Maintenance dose:
      i. Age ≥ 12 years: 300 mg every other week;
      ii. Age 6-11 years and weight ≥ 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: 12 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) as evidenced by chart notes:
   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 ≥ 12 weeks;
2. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist;
3. Age ≥ 12 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)* as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
5. Failure of maintenance therapy with at least one intranasal corticosteroid, used for ≥ 4 weeks, unless contraindicated or clinically significant adverse effects are experienced *(see Appendix B for examples)* as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
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 another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
8. Dose does not exceed 300 mg every other week.

**Approval duration: 12 months**

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

1. Diagnosis of EoE confirmed by ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf) on endoscopic biopsy as evidenced by chart notes;
2. Prescribed by or in consultation with an allergist, immunologist, or gastroenterologist;
3. Age ≥ 1 year;
4. Weight ≥ 15 kg;
5. Member does not have hypereosinophilic syndrome or eosinophilic granulomatosis with polyangiitis (formerly Churg-Strauss syndrome);
6. Failure of one of the following (a or b), unless clinically significant adverse effects are experienced or both are contraindicated as evidenced by prescription claims unless member is new to plan (<3 months eligibility):
   a. Proton pump inhibitor *(see Appendix B for examples)*;
   b. Corticosteroid *(see Appendix B for examples)*;
7. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
8. Dose does not exceed the following:
   a. Weight 15 to < 30 kg: 200 mg every other week;
   b. Weight 30 to < 40 kg: 300 mg every other week;
   c. Weight ≥ 40 kg: 300 mg every week.

**Approval duration: 12 months**

**E. Prurigo Nodularis** (must meet all)**:**

1. Diagnosis of PN with documentation of one of the following (a or b) as evidenced by chart notes:
   a. Numeric rating scale > 7 on a scale of 0 ("no itch") to 10 ("worst imaginable itch") (e.g., Peak Pruritus Numeric Rating Scale, Worst Itch-Numeric Rating Scale);
   b. ≥ 20 nodular lesions total on both legs, and/or both arms and/or trunk;
2. Prescribed by or in consultation with a dermatologist;
3. Age ≥ 18 years;
4. Failure of a ≥ 2-week course of a medium to very high potency topical corticosteroid, unless contraindicated or clinically significant adverse effects are experienced as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
5. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
6. Dose does not exceed the following:
   a. Initial (one-time) dose: 600 mg;
   b. Maintenance dose: 300 mg every other week.

**Approval duration: 12 months**

**F. Chronic Obstructive Pulmonary Disease** (must meet all):

1. Diagnosis of COPD as evidenced by one of the following (a or b) as evidenced by chart notes:

a. Postbronchodilator ratio of the forced expiratory volume in 1 second ($FEV_1$)/forced vital capacity (FVC) < 0.7;
b. Postbronchodilator $FEV_1 \geq 20$ % and ≤ 80% of predicted normal;

2. Age ≥ 18 years;
3. Documentation of eosinophilic phenotype with blood eosinophil count of ≥ 300 cells/µL as evidenced by chart notes;
4. Member has history of ≥ 2 moderate or ≥ 1 severe exacerbations within the past 12 months as evidenced by chart notes;
5. Member meets one of the following (a or b, *see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated as evidenced by prescription claims unless member is new to plan (<3 months eligibility):
   a. Failure of triple inhaled therapy consisting of a combination of LABA + long-acting antimuscarinic antagonist (LAMA) + ICS, at up to maximally indicated doses for ≥ 3 months;
   b. If member is contraindicated to ICS, failure of dual inhaled therapy consisting of a combination of LABA + LAMA, at up to maximally indicated doses for ≥ 3 months;
6. Provider attestation that member is concomitantly receiving triple therapy maintenance (e.g., LABA + LAMA + ICS) or double therapy maintenance (e.g., LABA + LAMA) if ICS is contraindicated;
7. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
8. Dose does not exceed 300 mg every other week.
   **Approval duration: 12 months**

**G. Chronic Spontaneous Urticaria** (must meet all)

1. Diagnosis of CSU;
2. Prescribed by or in consultation with a dermatologist, immunologist, or allergist;
3. Age ≥ 12 years;
4. Failure of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b) as evidenced by prescription claims unless member is new to plan (<3 months eligibility):
   a. Two antihistamines (including one second generation antihistamine – e.g., cetirizine, levocetirizine, fexofenadine, loratadine, desloratadine) at maximum indicated doses, each used for ≥ 2 weeks;
   b. A LTRA in combination with an antihistamine at maximum indicated doses for ≥ 2 weeks;
5. Member has not received prior anti-IgE treatment (e.g., Xolair) for CSU;
6. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
7. Dose does not exceed one of the following (a or b):
   a. Age ≥ 18 years, both of the following (i and ii):
      i. Initial (one-time) dose: 600 mg;

ii. Maintenance dose: 300 mg every other week;
b. Age 12-17 years, both of the following (i and ii):
i. Initial (one-time) dose (1 or 2):
1) Weight ≥ 60 kg: 600 mg;
2) Weight 30 to < 60 kg: 400 mg;
ii. Maintenance dose (1 or 2):
1) Weight ≥ 60 kg: 300 mg every other week;
2) Weight 30 to < 60 kg: 200 mg every other week.

**Approval duration: 12 months**

**H. Bullous Pemphigoid** (must meet all)**:**
1. Diagnosis of BP;
2. Diagnosis is confirmed histologically, serologically (e.g., anti-BP180 IgG autoantibodies and/or anti-BP230 IgG autoantibodies by ELISA), or by immunofluorescence as evidenced by chart notes
3. Prescribed by or in consultation with a dermatologist;
4. Age ≥ 18 years;
5. Inadequate response to at least one corticosteroid (e.g., prednisone) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
6. Failure of at least one non-steroidal immunosuppressive agent (e.g., azathioprine, mycophenolate mofetil, methotrexate) *(see Appendix B)* at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
7. Prescribed in combination with a tapering course of oral corticosteroid;
8. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
9. Dose does not exceed both of the following (a and b):
a. Initial (one-time) dose: 600 mg;
b. Maintenance dose: 300 mg every other week.

**Approval duration: 12 months**

**I. Allergic Fungal Rhinosinusitis** (must meet all)**:**
1. Diagnosis of AFRS as evidenced by chart notes with the presence of all of the following (a-d) :
a. Immunoglobulin E (IgE) mediated inflammatory response to fungal hyphae (i.e., positive skin test to fungus or positive fungal-specific IgE in serum);
b. Nasal polyposis;
c. Characteristic signs of AFRS on computed tomography (CT) scan (e.g., hyperdensities, bony demineralization, bone erosion of sinus);
d. Eosinophilic mucin/mucus;
2. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist;
3. Age ≥ 6 years;

4. Documentation of both of the following (a and b) as evidenced by chart notes:
   a. Evidence of sinus opacification on the Lund Mackay (LMK) sinus CT scan;
   b. LMK score of one of the following (i or ii):
      i. If member has unilateral polyps: ≥ 9;
      ii. If member has bilateral polyps: > 12;
5. Disease has recurred despite both of the following (a and b):
   a. Sino-nasal surgery as evidenced by chart notes;
   b. ≥ 4-week trial of corticosteroids (systemic and/or intranasal), unless clinically significant adverse effects are experienced or all are contraindicated *(see Appendix B for examples)* as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
6. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
7. Dose does not exceed one of the following (a, b, or c):
   a. Age ≥ 18 years or weight ≥ 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.

**Approval duration: 12 months**

**J. Immunotherapy-related Pruritus (off-label)** (must meet all)**:**

1. Diagnosis of immune checkpoint inhibitor-related toxicity that is one of the following (a or b; *see Appendix E*) as evidenced by chart notes:
   a. Pruritus that is moderate (G2) or severe (G3);
   b. Bullous dermatitis that is moderate (G2), severe (G3), or life-threatening (G4);
2. Prescribed by or in consultation with an oncologist;
3. For pruritus, member has not responded to a gabapentinoid (e.g., gabapentin, pregabalin) after 1 month of therapy as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
4. For bullous dermatitis, diagnosis of BP is confirmed by biopsy or serology as evidenced by chart notes;
5. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Xolair, or Tezspire;
6. Dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN*

**Approval duration: 12 months**

**K. 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 PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: 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.PMN.53 for Medicaid.

## II. Continued Therapy

### A. Atopic Dermatitis

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 chart notes, including but not limited to, reduction in itching and scratching;
3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed:
   a. Age ≥ 18 years or weight ≥ 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: 12 months**

### B. Asthma

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) as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
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) as evidenced by chart notes;
4. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
5. If request is for a dose increase, new dose does not exceed:
   a. Age ≥ 12 years: 300 mg every other week;
   b. Age 6-11 years and weight ≥ 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: 12 months**

**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 as evidenced by prescription claims unless member is new to plan (<3 months eligibility);
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) as evidenced by chart notes;
4. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
5. If request is for a dose increase, new dose does not exceed 300 mg every other week.

**Approval duration: 12 months**

**D. Eosinophilic Esophagitis** (must meet all)**:**
1. Currently 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) as evidenced by chart notes;

3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed the following:
   a. Weight 15 to < 30 kg: 200 mg every other week;
   b. Weight 30 to < 40 kg: 300 mg every other week;
   c. Weight ≥ 40 kg: 300 mg every week.

**Approval duration: 12 month**

**E. Prurigo Nodularis** (must meet all)**:**

1. Currently 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: improvement in itching or skin pain, reduction in number of nodules) as evidenced by chart notes;
3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed 300 mg every other week.

**Approval duration: 12 months**

**F. Chronic Obstructive Pulmonary Disease** (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 chart notes;
3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed 300 mg given every other week.

**Approval duration: 12 months**

**G. Chronic Spontaneous Urticaria** (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 chart notes;
3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed the following:
   a. Age ≥ 18 years or weight ≥ 60 kg: 300 mg every other week;
   b. Age 12-17 years and weight 30 to < 60 kg: 200 mg every other week.

**Approval duration: 12 months**

**H. Bullous Pemphigoid** (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 chart notes;
3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed 300 mg given every other week.

**Approval duration: 12 months**

**I. Allergic Fungal Rhinosinusitis** (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: improvement in sinus opacification [i.e., reduced LMK score], reduced sinus bone erosion, reduced nasal polyp size, reduced need for systemic corticosteroids or sino-nasal surgery, improved sense of smell, improved quality of life) as evidenced by chart notes;

3. Dupixent is not prescribed concurrently with another biologic immunomodulator (e.g., Adbry, Cinqair, Fasenra, Nucala, Tezspire, Xolair) or a JAK inhibitor (e.g., Olumiant, Rinvoq, Cibinqo, Opzelura);
4. If request is for a dose increase, new dose does not exceed one of the following (a, b, or c):
   a. Age ≥ 18 years or weight ≥ 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.

**Approval duration: 12 months**

**J. Immunotherapy-related Pruritus (off-label)** (must meet all)**:**
1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Dupixent for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy as evidenced by chart notes;
3. If request is for a dose increase, new dose is within FDA maximum limit for any FDA-approved indication or is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).*
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

**Approval duration: 12 months**

**K. 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 PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the PDL (Medicaid), the non-formulary policy for the relevant line of business: 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.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.PMN.53 for Medicaid or evidence of coverage documents;

**B.** Acute bronchospasm or status asthmaticus.

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

ADL: activity of daily living
CRSwNP: chronic rhinosinusitis with nasal polyposis
CSU: chronic spontaneous urticaria
EoE: eosinophilic esophagitis
eos/hpf: eosinophils per high-power field
FDA: Food and Drug Administration
GINA: Global Initiative for Asthma

ICS: inhaled corticosteroid
JAK: Janus kinase
LABA: long-acting beta$_2$ agonist
LTRA: leukotriene modifier
PDC: proportion of days covered
PN: prurigo nodularis
WI-NRS: Worst Itch-Numeric Rating Scale

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

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| **ATOPIC DERMATITIS, PN** | | |
| **Very High Potency Topical Corticosteroids** | | |
| augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion | Apply topically to the affected area(s) BID | Varies |
| clobetasol propionate 0.05% (Temovate® ) cream, ointment, gel, solution | | |
| diflorasone diacetate 0.05% (Maxiflor®, Psorcon E®) cream, ointment | | |
| fluocinonide 0.1% cream | | |
| flurandrenolide 4 mcg/cm$^2$ tape | | |
| halobetasol propionate 0.05% (Ultravate®) cream, ointment | | |
| **High Potency Topical Corticosteroids** | | |
| amcinonide 0.1% ointment, lotion | Apply topically to the affected area(s) BID | Varies |
| augmented betamethasone 0.05% (Diprolene® AF) cream, ointment, gel, lotion | | |
| betamethasone valerate 0.1%, 0.12% (Luxiq®) ointment, foam | | |
| clobetasol propionate 0.025% (Impoyz® ) cream | | |
| diflorasone 0.05% (Florone®, Florone E®, Maxiflor®, Psorcon E®) cream | | |
| fluocinonide acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| fluticasone propionate 0.005% cream, ointment | | |
| halcinonide 0.1% cream, ointment, solution (Halog®) | | |
| halobetasol propionate 0.01% lotion (Bryhali®) | | |
| mometasone furoate 0.1% ointment | | |
| triamcinolone acetonide 0.5% (Aristocort®, Kenalog®) cream, ointment | | |
| **Medium Potency Topical Corticosteroids** | | |
| clocortolone pivalate 0.1% cream | Apply topically to the affected area(s) BID | Varies |
| desoximetasone 0.05%, 0.25% (Topicort ®) cream, ointment, gel, spray | | |
| fluocinolone acetonide 0.025% (Synalar®) cream, ointment | | |
| flurandrenolide 0.05% lotion, ointment (Cordran®) | | |
| hydrocortisone valerate 0.2% cream | | |
| mometasone 0.1% (Elocon®) cream, ointment, lotion | | |
| triamcinolone acetonide 0.025%, 0.1% (Aristocort®, Kenalog®) cream, ointment | | |
| **Other Classes of Agents** | | |
| Protopic® (tacrolimus), Elidel® (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® (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 |
| **ASTHMA** | | |
| **ICS (medium – high dose)** | | |
| Qvar® (beclomethasone) | > 100 mcg/day<br>40 mcg, 80 mcg per actuation<br>1-4 actuations BID | 4 actuations BID |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| budesonide (Pulmicort®) | > 200 mcg/day<br>90 mcg, 180 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Alvesco® (ciclesonide) | > 80 mcg/day<br>80 mcg, 160 mcg per actuation<br>1-2 actuations BID | 2 actuations BID |
| fluticasone propionate (Flovent®) | > 100 mcg/day<br>44-250 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Arnuity Ellipta® (fluticasone furoate) | ≥ 50 mcg/day<br>100 mcg, 200 mcg per actuation<br>1 actuation QD | 1 actuation QD |
| Asmanex® (mometasone) | > 100 mcg/day<br>HFA: 100 mcg, 200 mcg per actuation<br>Twisthaler: 110 mcg, 220 mcg per actuation<br>1-2 actuations QD to BID | 2 inhalations BID |
| **LABA** | | |
| Serevent® (salmeterol) | 50 mcg per dose<br>1 inhalation BID | 1 inhalation BID |
| **Combination Products (ICS + LABA)** | | |
| Dulera® (mometasone/ formoterol) | 100/5 mcg, 200/5 mcg per actuation<br>2 actuations BID | 4 actuations per day |
| Breo Ellipta® (fluticasone/vilanterol) | 100/25 mcg, 200/25 mcg per actuation<br>1 actuation QD | 1 actuation QD |
| fluticasone/ salmeterol (Advair®) | Diskus: 100/50 mcg, 250/50 mcg, 500/50 mcg per actuation<br>HFA: 45/21 mcg, 115/21 mcg, 230/21 mcg per actuation<br>1 actuation BID | 1 actuation BID |
| fluticasone/salmeterol (Airduo RespiClick®) | 55/13 mcg, 113/14 mcg, 232/14 mcg per actuation<br>1 actuation BID | 1 actuation BID |
| budesonide/ formoterol (Symbicort®) | 80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation<br>2 actuations BID | 2 actuations BID |
| **LTRA** | | |
| montelukast (Singulair®) | 4 to 10 mg PO QD | 10 mg per day |
| zafirlukast (Accolate®) | 10 to 20 mg PO BID | 40 mg per day |
| zileuton ER (Zyflo® CR) | 1,200 mg PO BID | 2,400 mg per day |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Zyflo® (zileuton) | 600 mg PO QID | 2,400 mg per day |
| **Oral Corticosteroids** | | |
| dexamethasone (Decadron®) | 0.75 to 9 mg/day PO in 2 to 4 divided doses | Varies |
| methylprednisolone (Medrol®) | 40 to 80 mg PO in 1 to 2 divided doses | Varies |
| prednisolone (Millipred®, Orapred ODT®) | 40 to 80 mg PO in 1 to 2 divided doses | Varies |
| prednisone (Deltasone®) | 40 to 80 mg PO in 1 to 2 divided doses | Varies |
| **CRSwNP** | | |
| **Intranasal Corticosteroids** | | |
| beclomethasone (Beconase AQ®, Qnasl®) | 1-2 sprays IN BID | 2 sprays/nostril BID |
| budesonide (Rhinocort® Aqua, Rhinocort®) | 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®) | 1-2 sprays IN BID | 2 sprays/nostril BID |
| mometasone (Nasonex®) | 2 sprays IN BID | 2 sprays/nostril BID |
| Omnaris®, Zetonna® (ciclesonide) | Omnaris: 2 sprays IN QD<br>Zetonna: 1 spray IN QD | Omnaris: 2 sprays/ nostril/day<br>Zetonna: 2 sprays/ nostril/day |
| triamcinolone (Nasacort®) | 2 sprays IN QD | 2 sprays/ nostril/day |
| Xhance™ (fluticasone propionate) | 1 to 2 sprays (93 mcg/spray) to nostril IN BID | 744 mcg/day |
| **Oral Corticosteroids** | | |
| dexamethasone (Decadron®) | 0.75 to 9 mg/day PO in 2 to 4 divided doses | Varies |
| methylprednisolone (Medrol®) | 4 to 48 mg PO in 1 to 2 divided doses | Varies |
| prednisolone (Millipred®, Orapred ODT®) | 5 to 60 mg PO in 1 to 2 divided doses | Varies |
| prednisone (Deltasone®) | 5 to 60 mg PO in 1 to 2 divided doses | Varies |
| **EoE** | | |
| Corticosteroids: examples –<br>• Topical:<br>○ Budesonide administered as an oral viscous slurry of budesonide inhalation suspension [Pulmicort | Varies | Varies |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Respules®] with sucralose or similar carrier vehicle<br>○ Fluticasone propionate administered using a metered dose inhaler<br>• Oral:<br>○ Prednisone | | |
| Proton pump inhibitors (e.g., omeprazole, esomeprazole, lansoprazole, rabeprazole, pantoprazole) | Varies | Varies |
| **COPD** | | |
| *ICS/LABA Combinations* | | |
| fluticasone/salmeterol (Advair Diskus®) | Refer to prescribing information | Refer to prescribing information |
| Breo Ellipta® (fluticasone/vilanterol) | | |
| budesonide/formoterol (Symbicort®) | | |
| Dulera®* (mometasone/formoterol) | Doses of 10 mcg formoterol/400 mcg mometasone and 10 mcg formoterol/ 200 mcg mometasone, each inhaled BID, have been studied | The optimal dose has not been established |
| *LABA/LAMA Combinations* | | |
| Bevespi Aerosphere® (formoterol/glycopyrrolate) | Refer to prescribing information | Refer to prescribing information |
| Utibron Neohaler® (indacaterol/glycopyrrolate) | | |
| Anoro Ellipta® (vilanterol/umeclidinium) | | |
| Stiolto Respimat® (olodaterol/tiotropium) | | |
| *LAMAs* | | |
| Tudorza Pressair® (aclidinium bromide) | Refer to prescribing information | Refer to prescribing information |
| Seebri Neohlaer® (glycopyrrolate) | | |
| Spiriva Respimat®/ HandiHaler® (tiotropium) | | |
| Incruse Ellipta® (umeclidinium) | | |
| *LABAs* | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Brovana® (arformoterol) | Refer to prescribing information | Refer to prescribing information |
| Arcapta Neohaler® (indacterol) | | |
| Striverdi Respimat® (olodaterol) | | |
| Serevent Diskus® (salmeterol) | | |
| ICS/LABA/LAMA Combinations | | |
| Trelegy™ Ellipta® (fluticasone/umeclidinium/ vilanterol) | 1 inhalation by mouth QD | 1 inhalation/day |
| **IMMUNOTHERAPY-RELATED MODERATE (G2) BULLOUS DERMATITIS** | | |
| corticosteroids: examples – prednisone, IV methylprednisolone | 1-2 mg/kg/day<br>Treat until symptoms improve to Grade ≤ 1, then taper over 4–6 weeks. | Varies |
| **CSU** | | |
| hydroxyzine (Vistaril®) | Adult: 25 mg PO TID to QID<br>Age ≥ 6 years: 50 mg-100 mg/day in divided doses | Adult: Will vary according to condition<br>Age ≥ 6 years: 50 mg-100 mg/day in divided doses |
| diphenhydramine (Benadryl®) | Adult: 25 mg to 50 mg PO TID to QID<br>Pediatric: 12.5 mg to 25 mg PO TID to QID or 5 mg/kg/day or 150 mg/m²/day | Adult: Will vary according to condition<br>Children: 300 mg/day |
| chlorpheniramine (Aller- Chlor®) | Immediate Release: 4 mg PO every 4 to 6 hours<br>Extended Release: 12 mg PO every 12 hours | Do not exceed 24 mg/day |
| cetirizine (Zyrtec®) | 5 to 10 mg PO QD | 10 mg/day |
| levocertirizine (Xyzal®) | 2.5 mg to 5 mg PO QD | 5 mg/day |
| loratadine (Claritin®) | 10 mg PO QD | 10 mg/day |
| desloratadine (Clarinex®) | 5 mg PO QD | Will vary according to condition |
| fexofenadine (Allegra®) | 60 mg PO BID or 180 mg QD | 180 mg/day |

*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 6 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.
  - 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/eosinophil-calculator.
  - 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.
- CSU:
  - CSU is classified as spontaneous onset of wheals, angioedema, or both, for more than 6 weeks due to an unknown cause.
  - Clinical studies have shown that dupilumab significantly improved the signs and symptoms of chronic idiopathic urticaria compared to placebo in patients who had remained symptomatic despite the use of approved dose of $H_1$- antihistamine. Dupilumab was also studied in patients who remained symptomatic despite $H_1$-antihistamine and anti-IgE treatments (CUPID Study B), but did not meet statistical significance for reduction in the primary endpoint Itch Severity Score over 7 days (ISS7) at Week 24.
  - Dupilumab for CSU is not currently included in clinical guideline treatment algorithms.
    - The 2014 Joint Task Force on Practice Parameters representing various American allergy organizations include omalizumab in combination with H1-antihistamines as a fourth line treatment option following a stepwise approach starting with a second generation antihistamine. This is followed by one or more of the following: a dose increase of the second generation antihistamine, or the addition of another second generation antihistamine, H2-antagonist, LTRA, or first generation antihistamine. Treatment with hydroxyzine or doxepin can be considered in patients whose symptoms remain poorly

controlled.
    - The EAACI/GA2LEN/EDF/AAAAI/WAO Guideline for the Management of Urticaria include omalizumab in combination with $H_1$-antihistamines as a third line treatment option in patients who have failed to respond to higher doses of $H_1$- antihistamines.
  - The use of over-the-counter $H_1$ antihistamines may not be a benefit to the treatment of CSU. Credit will be given for their use, but will not be covered under plan.

*Appendix E: Immunotherapy-related Pruritus*

- Immunotherapy refers to immune checkpoint inhibitors. Immune checkpoint inhibitors comprise a class of agents that target immune cell checkpoints, such as programmed cell death-1 (PD-1; e.g., Opdivo®, Keytruda®) and PD-1 ligand (PD-L1; e.g., Tecentriq®, Bavencio®, Imfinzi®), as well as cytotoxic T-lymphocyte–associated antigen 4 (e.g., Yervoy®, Imjudo®).
- NCCN grading of pruritus
  - G1: Mild or localized
  - G2: Moderate. Intense or widespread; intermittent; skin changes from scratching (e.g., edema, papulation, excoriations, lichenification, oozing/crusts); limiting instrumental activities of daily living (ADLs)
  - G3: Severe. Intense or widespread; constant; limiting self-care ADLs or sleep
- NCCN grading of bullous dermatitis
  - G1: Asymptomatic; blisters covering < 10% BSA
  - G2: Blisters covering 10%-30% BSA; painful blisters; limiting instrumental ADLs
  - G3: Blisters covering > 30% BSA; limiting self-care ADLs
  - G4: Blisters covering > 30% BSA; associated with fluid or electrolyte abnormalities; intensive care unit (ICU) care or burn unit indicated

## V. Dosage and Administration

| | | |
|---|---|---|
| Moderate-to-severe atopic dermatitis | *Adults*: Initial dose of 600 mg SC followed by 300 mg SC every other week<br><br>*Adolescents 6-17 years of age*:<br>• Body weight 15 to < 30 kg: Initial dose of 600 mg SC followed by 300 mg SC every 4 weeks<br>• Body weight 30 kg to < 60 kg: Initial dose of 400 mg SC followed by 200 mg SC every other week<br>• Body weight ≥ 60 kg: Initial dose of 600 mg SC followed by 300 mg SC every other week | See regimen |

| | | |
|---|---|---|
| | *Pediatrics 6 months - 5 years of age*:<br>• Body weight 5 to < 15 kg: 200 mg SC every 4 weeks<br>• Body weight 15 to < 30 kg: 300 mg SC every 4 weeks | |
| Moderate-to-severe asthma | *Adults and adolescents (12 years and older)*:<br>Initial dose of 400 mg SC followed by 200 mg SC every other week; or<br>Initial dose of 600 mg SC followed by 300 mg SC every other week<br><br>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<br><br>*Adolescents 6-11 years of age*:<br>• Body weight 15 to < 30 kg: Initial dose and subsequent dose of 300 mg SC every four weeks<br>• Body weight ≥ 30 kg: Initial dose and subsequent dose of 200 mg SC every other week<br><br>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 | See regimen |
| CRSwNP | 300 mg SC every other week | 300 mg every other week |
| EoE | *Adult and pediatric patients ≥ 1 year of age, weight ≥ 15 kg*:<br>• Body weight 15 to < 30 kg: 200 mg SC every other week<br>• Body weight 30 to < 40 kg: 300 mg SC every other week<br>• Body weight ≥ 40 kg: 300 mg SC every week | 300 mg/week |
| PN | Initial dose of 600 mg SC followed by 300 mg SC every other week | See regimen |
| COPD | 300 mg SC every other week | 300 mg SC every other week |
| CSU | Age ≥ 18 years: | See regimen |

| | | |
|---|---|---|
| | • Initial (one-time) dose: 600 mg SC<br>• Maintenance dose: 300 mg SC every other week<br><br>Age 12-17 years:<br>• Initial (one-time) dose:<br>  ○ Weight ≥ 60 kg: 600 mg SC<br>  ○ Weight 30 to < 60 kg: 400 mg SC<br>• Maintenance dose:<br>  ○ Weight ≥ 60 kg: 300 mg SC every other week<br>  ○ Weight 30 to < 60 kg: 200 mg SC every other week | |
| BP | Initial dose of 600 mg SC followed by 300 mg SC every other week | See regimen |

## VI. Product Availability*

- Pre-filled syringes with needle shield for injection: 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 for use in adult and pediatric patients aged 2 years and older, while the pre-filled syringe is for use in adult and pediatric patients aged 6 months and older. In pediatric patients 12 to 17 years of age, Dupixent should be administered under the supervision of an adult. In pediatric patients 6 months to less than 12 years of age, Dupixent should be administered by a caregiver.*

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***Immunotherapy-related Pruritus***

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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 |
|---|---|---|
| New policy created, split from CP.PHAR.336 Dupilumab (Dupixent). Changed Atopic Dermatitis initial criteria from requiring 2 TCS to One TCS. Changed CRSwNP initial criteria from requiring two intranasal corticosteroids to one intranasal corticosteroid. Changed Prurigo Nodularis from requiring both the WI-NRS rating scale and total lesion count to requiring one or the other. This is a request from Department of Community Health request (DCH) to align with their criteria. | 07/24 | 07/24 |
| RT4: Updated approved indication to include pediatric patients aged 12 years and older for chronic rhinosinusitis with nasal polyps (CRSwNP). RT4: added newly approved COPD indication to criteria. For prurigo nodularis initial approval criteria, updated diagnosis criteria from "WI-NRS ≥ 7 on a scale of 0 to 10" to "Numeric rating scale > 7 on a scale of 0 ("no itch") to 10 ("worst imaginable itch") (e.g., Peak Pruritus Numeric Rating Scale, Worst Itch-Numeric Rating Scale)" to align with Nemluvio criteria. For immunotherapy-related pruritus per NCCN, removed "refractory" for G3 pruritus, added requirement for no response to 1 month of gabapentinoid therapy for severe pruritus, removed requirement for increased IgE level, and added indication for immunotherapy-related bullous dermatitis; references reviewed and updated. | 01/25 | 01/25 |
| 3Q 2025 annual review. No changes made. | 06/25 | 06/25 |

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|---|---|---|
| RT4: added new indication for CSU per updated prescribing information. Per SDC: for COPD, revised postbronchodilator $FEV_1$ requirement from 30-70% to 20-80% to align with Nucala. references reviewed and updated. | 09/25 | 09/25 |
| RT4: added new indication for BP per updated prescribing information and P&T-approved clinical guidance. Removed 100 mg/0.67 mL pre-filled syringe as it is no longer commercially available. | 12/25 | 12/25 |
| For all labeled indications, extended initial approval duration from 6 to 12 months for this maintenance medication for a chronic condition; per NCCN for immunotherapy-related toxicity, added option for G2 pruritus, added requirement for diagnostic confirmation of BP for bullous dermatitis, and removed corticosteroid requirement for bullous dermatitis; for immunotherapy-related toxicity, revised approval durations from 6 to 12 months; references reviewed and updated. | 2/26 | 2/26 |
| 2Q 2026 annual review. Added new indication for AFRS per updated prescribing information. References reviewed and updated. | 6/26 | 6/26 |
| Added language to criteria for supporting chart notes and/or prescription claims records and removed language regarding Commercial and HIM line of businesses since this a Medicaid policy. | 7/26 | 7/26 |

**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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

**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.