Clinical Policy: Dupilumab (Dupixent)

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Line of Business: Meridian Illinois 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 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 40 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 2 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
2. Prescribed by or in consultation with a dermatologist or allergist;

3. Age ≥ 6 months;
4. Failure of one medium to very high potency topical corticosteroid within the past year and one of the following within the past 2 years (a, b, c, or d), unless contraindicated or clinically significant adverse effects are experienced:
    a. Generic Immunosuppressant (IS) if appropriate;
    b. Topical calcineurin inhibitors (TCI);
    c. Phototherapy (PT);
    d. Phosphodiesterase-4 inhibitor (PDE-4)
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: 6 months

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

1. Diagnosis of asthma and one of the following (a, b or c):
    a. Absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months;
    b. Oral corticosteroid dependent asthma;
    c. Member has a Forced Expiratory Volume (FEV1) that is less than 80% predicted for adults or less than 90% for adolescents and has been treated consistently with a leukotriene modifier OR medium-high/max-tolerated ICS + controller OR max-tolerated ICS/LABA combo;
2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
3. Age ≥ 6 years;
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. 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: 6 months

C. Chronic Rhinosinusitis with Nasal Polyposis (must meet all)**:**
1. Confirmed diagnosis of CRSwNP
2. Prescribed by or in consultation with an allergist, pulmonologist, or otolaryngologist;
3. Age ≥ 12 years;
4. One of the following
   a. Member has had prior nasal surgery OR
   b. Member CRSwNP is inadequately controlled by medical therapy with two of the following:
      1. Intranasal corticosteroids (INS) within the past year;
      2. Systemic corticosteroid therapy (SCS);
      3. Nasal nebulized solution of budesonide;
      4. Contraindication or intolerance to SCS;
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 300 mg every other week.

Approval duration: 6 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;
2. Prescribed by or in consultation with an allergist, immunologist, or gastroenterologist;
3. Age ≥ 1 years;
4. Weight ≥ 15 kg;
5. Member does not have hypereosinophilic syndrome or eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome);
6. Failure of the following (a and b), unless clinically significant adverse effects are experienced, or both are contraindicated:
   a. Use of Proton pump inhibitor for 8 weeks (see Appendix B for examples)
   b. Topical glucocorticocoid (fluticasone using MDI without a spacer or budesonide administered as an oral slurry);
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 week.

Approval duration: 6 months

E. Prurigo Nodularis (must meet all)**:**
1. Diagnosis of PN with documentation of both of the following (a and b):
   a. Worst Itch-Numeric Rating Scale (WI-NRS) ≥ 7 on a scale of 0 ("no itch") to 10 ("worst imaginable itch");
   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;

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: 6 months

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

1. Diagnosis of COPD as evidenced by one of the following (a or b):
   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;
4. Member has history of ≥ 2 moderate or ≥ 1 severe exacerbations within the past 12 months;
5. Member meets one of the following (a or b, *see Appendix B*), unless clinically significant adverse effects are experienced or all are contraindicated:
   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: 6 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 ≥ 2 years;
4. Failure of both of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Two antihistamines (including one second generation antihistamine – e.g., cetirizine, levocetirizine, fexofenadine, loratadine) 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.
   c. Age 2-5 years, one of the following (i or ii):
      i. Weight 5 to < 15 kg: 200 mg every 4 weeks;
      ii. Weight 15 to < 30 kg: 300 mg every 4 weeks.

Approval duration: 6 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;
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;
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;
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: 6 months

I. Immunotherapy-related Toxicity (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*):
   a. Pruritus that is moderate (G2) or severe (G3);
   b. Bullous dermatitis that is moderate (G2), severe (G3), or life-threatening (G4);
2. For pruritus, member has not responded to a gabapentinoid (e.g., gabapentin, pregabalin) after 1 month of therapy;

3. For bullous dermatitis, diagnosis of BP is confirmed by biopsy or serology;
4. Prescribed by or in consultation with an oncologist;
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: 6 months

J. 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.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.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 (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 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:
Medicaid – 12 months

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 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:
Medicaid– 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;
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 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:
Medicaid – 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);
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 week.

Approval duration:
Medicaid – 12 months

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);
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:
Medicaid – 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;
3. 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;
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 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;
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 6-17 years (i or ii):
      i. Weight 30 to < 60 kg: 200 mg every other week;
      ii. Weight 15 to < 30 kg: 300 mg every 4 weeks;
   c. Age 2-5 years (i or ii):
      i. Weight 5 to < 15 kg: 200 mg every 4 weeks;
      ii. Weight 15 to < 30 kg: 300 mg every 4 weeks.

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;
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. Immunotherapy-related Toxicity (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;
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

J. 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.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.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

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
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.

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		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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		
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®)		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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)	> 200 mcg/day 40 mcg, 80 mcg per actuation 1-4 actuations BID	4 actuations BID
budesonide (Pulmicort®)	> 400 mcg/day 90 mcg, 180 mcg per actuation 2-4 actuations BID	2 actuations BID
Alvesco® (ciclesonide)	> 160 mcg/day 80 mcg, 160 mcg per actuation 1-2 actuations BID	2 actuations BID
Aerospan® (flunisolide)	> 320 mcg/day 80 mcg per actuation 2-4 actuations BID	2 actuations BID
Flovent® (fluticasone propionate)	> 250 mcg/day 44-250 mcg per actuation 2-4 actuations BID	2 actuations BID
Arnuity Ellipta® (fluticasone furoate)	200 mcg/day 100 mcg, 200 mcg per actuation 1 actuation QD	1 actuation QD
Asmanex® (mometasone)	>220 mcg/day HFA: 100 mcg, 200 mcg per actuation Twisthaler: 110 mcg, 220 mcg per actuation	2 inhalations BID

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	1-2 actuations QD to BID	
LABA		
Serevent® (salmeterol)	50 mcg per dose 1 inhalation BID	1 inhalation BID
Combination Products (ICS + LABA)		
Dulera® (mometasone/ formoterol)	100/5 mcg, 200/5 mcg per actuation 2 actuations BID	4 actuations per day
Breo Ellipta® (fluticasone/vilanterol)	100/25 mcg, 200/25 mcg per actuation 1 actuation QD	1 actuation QD
Advair® (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®)	55/13 mcg, 113/14 mcg, 232/14 mcg per actuation 1 actuation BID	1 actuation BID
Symbicort® (budesonide/ formoterol)	80 mcg/4.5 mcg, 160 mcg/4.5 mcg per actuation 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
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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 Zetonna: 1 spray IN QD	Omnaris: 2 sprays/ nostril/day 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 – • Topical: o Budesonide administered as an oral viscous slurry of budesonide inhalation suspension [Pulmicort Respules®] with sucralose or similar carrier vehicle o Fluticasone propionate administered using a metered dose inhaler • Oral: o Prednisone	Varies	Varies
Proton pump inhibitors (e.g., omeprazole, esomeprazole, lansoprazole, rabeprazole, pantoprazole)	Varies	Varies
ICS/LABA Combinations		
fluticasone/salmeterol (Advair Diskus®)	Refer to prescribing information	Refer to prescribing information
Breo Ellipta® (fluticasone/vilanterol)		

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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		
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
corticosteroids: examples – prednisone, IV methylprednisolone	1-2 mg/kg/day Treat until symptoms improve to Grade ≤ 1, then taper over 4–6 weeks.	Varies

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
corticosteroids: examples – prednisone, IV methylprednisolone	1-2 mg/kg/day Treat until symptoms improve to Grade ≤ 1, then taper over 4–6 weeks.	Varies
hydroxyzine (Vistaril®)	Adult: 25 mg PO TID to QID Age ≥ 6 years: 50 mg-100 mg/day in divided doses	Adult: Will vary according to condition Age ≥ 6 years: 50 mg-100 mg/day in divided doses
diphenhydramine (Benadryl®)	Adult: 25 mg to 50 mg PO TID to QID 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 Children: 300 mg/day
chlorpheniramine (Aller- Chlor®)	Immediate Release: 4 mg PO every 4 to 6 hours 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

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.
**off-label*

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.
- 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.
    - 2021 international guidelines (EAACI/GA^{2}LEN/EuroGuiDerm [also known as EDF]/APAAACI) recommend omalizumab as a second line therapy as add-on treatment for patients who have failed to respond to high dose (up to 4x the standard dose) second generation 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 Toxicity

- 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

Appendix F: Numerical Rating Scale

- The Peak Pruritus Numerical Rating Scale (PP-NRS) and the Worst Itch Numeric Rating Scale (WI-NRS) are single-item, patient-reported outcome measures for assessing the maximum severity of itch in people with pruritic skin disorders. The PP-NRS and WI-NRS assess the intensity of itch "at the worst moment during the previous 24 hours" on a scale of 0 ("no itch") to 10 ("worst itch imaginable").

V. Dosage and Administration

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

Indication	Dosing Regimen	Maximum Dose
	Pediatrics 6 months - 5 years of age: • Body weight 5 to < 15 kg: 200 mg SC every 4 weeks • Body weight 15 to < 30 kg: 300 mg SC every 4 weeks	
Moderate-to-severe asthma	*Adults and adolescents (12 years and older)*: 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 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 *Adolescents 6-11 years of age*: • Body weight 15 to < 30 kg: Initial dose and subsequent dose of 100 mg SC every other week or 300 mg every four weeks • Body weight ≥ 30 kg: Initial dose and subsequent dose of 200 mg SC every other week 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	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: • Initial (one-time) dose: 600 mg SC • Maintenance dose: 300 mg SC every other week Age 12-17 years: • Initial (one-time) dose:	See regimen

Indication	Dosing Regimen	Maximum Dose
	○ Weight ≥ 60 kg: 600 mg SC ○ Weight 30 to < 60 kg: 400 mg SC • Maintenance dose: ○ Weight ≥ 60 kg: 300 mg SC every other week 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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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
Policy created, adapted from CP. PHAR.336	04.01.22	04.22
Added EoE criteria per HFS PDL	11.13.22	
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. References reviewed and updated	1.6.23	
Clarified duration for Eosinophilic Esophagitis	9.29.23	
Added Prurigo Nodularis to Initial and Continuing criteria	10.20.23	
Clarified initial approval language for CRSwNP	11.15.23	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Initial criteria for EoE updated per recent FDA label change; off label immunotherapy related pruritis indication added	2.11.24	
Added appendix E	5.28.24	
1Q2025 Annual Review: Updated approved indication to include pediatric patients aged 12 years and older for chronic rhinosinusitis with nasal polyps (CRSwNP); added newly approved COPD indication to 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.	1.10.25	
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; 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.	11.21.25	
1Q 2026 annual review: 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; references reviewed and updated.	2.11.26	
For CSU, revised age requirement from age ≥ 12 years to ≥ 2 years to reflect pediatric extension per updated prescribing information. For EoE, revised the age from ≥ 12 years to ≥ 1 years per prescribing information. Added new indication for AFRS per updated prescribing information.	11.02.26	

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.

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contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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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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