

Clinical Policy: Dupilumab (Dupixent)

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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 patients aged 6 months and older with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent can be used with or without topical corticosteroids.
- As an add-on maintenance treatment in patients with moderate-to-severe asthma aged 6 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- As an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
- For the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).

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

Policy/Criteria

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

It is the policy of health plans affiliated with Centene Corporation[®] that Dupixent is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all):

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

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- b. One non-steroidal topical therapy* used for ≥ 4 weeks: topical calcineurin inhibitor (e.g., tacrolimus 0.03% ointment or Eucrisa[®]);
**These agents may require prior authorization*
- 5. Dupixent is not prescribed concurrently with Cinqair[®], Fasentra[®], Nucala[®], Tezspire[™], or Xolair[®];
- 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 or b):
 - a. Absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months;
 - b. Currently receiving maintenance treatment with systemic glucocorticoids and has received treatment for at least 4 weeks;
- 2. Prescribed by or in consultation with an allergist, immunologist, or pulmonologist;
- 3. Age ≥ 6 years;
- 4. Member has experienced ≥ 1 exacerbations within the last 12 months, requiring any of the following despite adherent use of controller therapy (i.e., medium- to high-dose inhaled corticosteroid [ICS] plus either a long-acting beta₂ agonist [LABA] or leukotriene modifier [LTRA] if LABA contraindication/intolerance):
 - a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid);
 - b. Urgent care visit or hospital admission;
 - c. Intubation;
- 5. Dupixent is prescribed concurrently with an ICS plus either a LABA or LTRA;
- 6. Dupixent is not prescribed concurrently with Cinqair, Fasentra, Nucala, Tezspire, or Xolair;
- 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: 6 months

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

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1. Diagnosis of CRSwNP with documentation of all of the following
 - a. Presence of nasal polyps;
2. Prescribed by or in consultation with an allergist, immunologist, or otolaryngologist;
3. Age \geq 18 years;
4. Member has required the use of systemic corticosteroids for symptom control within the last 2 years, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B for examples*);
5. Failure of maintenance therapy with at least one intranasal corticosteroids each used for \geq 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B for examples*);
6. Dupixent is prescribed concurrently with an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B for examples*);
7. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
8. Dose does not exceed 300 mg every other week.

Approval duration: 6 months

D. Eosinophilic Esophagitis (must meet all):

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

Approval duration: 6 months

E. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Atopic Dermatitis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy as evidenced by, including but not limited to, reduction in itching and scratching;

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3. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
4. If request is for a dose increase, new dose does not exceed:
 - a. Age \geq 18 years or weight \geq 60 kg: 300 mg every other week;
 - b. Age 6-17 years and weight 30 to $<$ 60 kg: 200 mg every other week;
 - c. Age 6-17 years and weight 15 to $<$ 30 kg: 300 mg every 4 weeks;
 - d. Age 6 months to 5 years and weight 5 to $<$ 15 kg: 200 mg every 4 weeks;
 - e. Age 6 months to 5 years and weight 15 to $<$ 30 kg: 300 mg every 4 weeks.

Approval duration:

Medicaid – 12 months

B. Asthma (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Demonstrated adherence to asthma controller therapy (an ICS plus either a LABA or LTRA) as evidenced by proportion of days covered (PDC) of 0.8 in the last 6 months (i.e., member has received asthma controller therapy for at least 5 of the last 6 months);
3. Member is responding positively to therapy (examples may include but are not limited to: reduction in exacerbations or corticosteroid dose, improvement in forced expiratory volume over one second since baseline, reduction in the use of rescue therapy);
4. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
5. If request is for a dose increase, new dose does not exceed:
 - a. Age \geq 12 years: 300 mg every other week;
 - b. Age 6-11 years and weight \geq 30 kg: 200 mg every other week;
 - c. Age 6-11 years and weight 15 to $<$ 30 kg: 300 mg every 4 weeks.

Approval duration:

Medicaid – 12 months

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

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Demonstrated adherence to an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;
3. Member is responding positively to therapy (examples may include but are not limited to: reduced nasal polyp size, reduced need for systemic corticosteroids, improved sense of smell, improved quality of life);
4. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, Tezspire, or Xolair;
5. If request is for a dose increase, new dose does not exceed 300 mg every other week.

Approval duration:

Medicaid – 12 months

D. Eosinophilic Esophagitis (must meet all):

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1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy (examples may include but are not limited to: reduced eos/hpf count, improvement in dysphagia symptoms);
3. Dupixent is not prescribed concurrently with Cinqair, Fasenna, Nucala, Tezspire, or Xolair;
4. If request is for a dose increase, new dose does not exceed 300 mg every week.

Approval duration:

Medicaid – 12 months

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

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): 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
 LABA: long-acting beta₂ agonist
 LTRA: leukotriene modifier
 PDC: proportion of days covered

Appendix B: Therapeutic Alternatives

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ATOPIC DERMATITIS		
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		

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
diflorasone diacetate 0.05% (Maxiflor [®] , Psorcon E [®]) cream, ointment		
halobetasol propionate 0.05% (Ultravate [®]) cream, ointment		
High Potency Topical Corticosteroids		
augmented betamethasone 0.05% (Diprolene [®] AF) cream, ointment, gel, lotion	Apply topically to the affected area(s) BID	Varies
diflorasone 0.05% (Florone [®] , Florone E [®] , Maxiflor [®] ,Psorcon E [®]) cream		
fluocinonide acetone 0.05% (Lidex [®] , Lidex E [®]) cream, ointment, gel, solution		
triamcinolone acetone 0.5% (Aristocort [®] , Kenalog [®]) cream, ointment		
Medium Potency Topical Corticosteroids		
desoximetasone 0.05% (Topicort [®]) cream, ointment, gel	Apply topically to the affected area(s) BID	Varies
fluocinolone acetone 0.025% (Synalar [®]) cream, ointment		
mometasone 0.1% (Elocon [®]) cream, ointment, lotion		
triamcinolone acetone 0.025%, 0.1% (Aristocort [®] , Kenalog [®]) cream, ointment		
Low Potency Topical Corticosteroids		
alclometasone 0.05% (Aclovate [®]) cream, ointment	Apply topically to the affected area(s) BID	Varies
desonide 0.05% (Desowen [®]) cream, ointment, lotion		
fluocinolone acetone 0.01% (Synalar [®]) solution		
hydrocortisone 2.5% (Hytone [®]) 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	Varies

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	should be discontinued if resolution of disease occurs.	
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 1-2 actuations QD to BID	2 inhalations 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

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
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
Omnanis [®] , Zetonna [®] (ciclesonide)	Omnanis: 2 sprays IN QD Zetonna: 1 spray IN QD	Omnanis: 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

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Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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 – <ul style="list-style-type: none"> • Topical: <ul style="list-style-type: none"> ○ Budesonide administered as an oral viscous slurry of budesonide inhalation suspension [Pulmicort Respules[®]] with sucralose or similar carrier vehicle ○ Fluticasone propionate administered using a metered dose inhaler • Oral: <ul style="list-style-type: none"> ○ Prednisone 	Varies	Varies
Proton pump inhibitors (e.g., omeprazole, esomeprazole, lansoprazole, rabeprazole, pantoprazole)	Varies	Varies

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.

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

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- (95% CI, 0.58 to 0.95) with higher-dose dupilumab and 0.64 (95% CI, 0.44 to 0.93) with matched placebo.
- The Global Initiative for Asthma (GINA) guidelines for difficult-to-treat and severe asthma recommend Dupixent be considered as adjunct therapy for patients 12 years of age and older with exacerbations or poor symptom control despite taking at least high dose ICS/LABA and who have eosinophilic biomarkers or need maintenance oral corticosteroids. Dupixent may also be considered if the patient is uncontrolled on Step 4 treatment (medium dose ICS/LABA).
 - Patients could potentially meet asthma criteria for both Xolair and Dupixent, though there is insufficient data to support the combination use of multiple asthma biologics. The combination has not been studied. Approximately 30% of patients in the Nucala MENSA study also were candidates for therapy with Xolair.
 - Lab results for blood eosinophil counts can be converted into cells/mcL using the following unit conversion calculator: <https://www.fasenrahcp.com/m/fasenra-eosinophil-calculator.html>
 - PDC is a measure of adherence. PDC is calculated as the sum of days covered in a time frame divided by the number of days in the time frame. To achieve a PDC of 0.8, a member must have received their asthma controller therapy for 144 days out of the last 180 days, or approximately 5 months of the last 6 months.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Moderate-to-severe atopic dermatitis	<p><i>Adults:</i> Initial dose of 600 mg SC followed by 300 mg SC every other week</p> <p><i>Adolescents 6-17 years of age:</i></p> <ul style="list-style-type: none"> • 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 <p><i>Pediatrics 6 months - 5 years of age:</i></p> <ul style="list-style-type: none"> • Body weight 5 to < 15 kg: 200 mg SC every 4 weeks • Body weight 15 to < 30 kg: 300 mg SC every 4 weeks 	See regimen
Moderate-to-severe asthma	<p><i>Adults and adolescents (12 years and older):</i> Initial dose of 400 mg SC followed by 200 mg SC every other week; or Initial dose of 600 mg SC followed by 300 mg SC every other week</p>	See regimen

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Indication	Dosing Regimen	Maximum Dose
	<p>For patients requiring concomitant oral corticosteroids or with co-morbid moderate-to-severe atopic dermatitis for which Dupixent is indicated, start with an initial dose of 600 mg SC followed by 300 mg SC every other week</p> <p><i>Adolescents 6-11 years of age:</i></p> <ul style="list-style-type: none"> • 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 \geq 30 kg: Initial dose and subsequent dose of 200 mg SC every other week <p>For pediatric patients (6 to 11 years old) with asthma and co-morbid moderate-to-severe atopic dermatitis, follow the recommended adolescent atopic dermatitis dosing, which includes an initial loading dose</p>	
CRSwNP	300 mg SC every other week	300 mg every other week
EoE	300 mg SC every week	300 mg/week

VI. Product Availability*

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

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

VII. References

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Coding Implications

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

HCPCS Codes	Description
C9399; J3590	Unclassified drugs or biologicals

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.22	11.22
Revision: AD: revise redirection from two to one very high potency corticosteroids (A4) and removal of double step edit (5). Revise eligibility to failure of 2steps through topical therapy. For CRSwNP removal of edits for parity to label – Disease is bilateral and signs and symptoms for => 12 weeks (1B and 1C). Update failure of of maintenance therapy from three to one intranasal corticosteroid for parity to label	4.23	6.23

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

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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.

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