# Clinical Policy: Dupilumab (Dupixent)

Reference Number: MDN.CP.PHAR.336
Effective Date: 04.01.22
Last Review Date: 04.22
Line of Business: Meridian IL 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 years 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)

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 years;
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 Cinqair®, Fasenra®, Nucala®, or Xolair®;
6. Dose does not exceed the following:
   a. Initial (one-time) dose:
      i. Age ≥ 18 years, weight ≥ 60 kg, or age 6-17 years and weight 15 to < 30 kg: 600 mg;
      ii. Age 6-17 years and weight 30 to < 60 kg: 400 mg;
   b. Maintenance dose:
      i. Age ≥ 18 years or weight ≥ 60 kg: 300 mg every other week;
      ii. Age 6-17 years and weight 30 to < 60 kg: 200 mg every other week;
      iii. 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 moderate to severe asthma and one of the following (a, b, or c):
   a. Absolute blood eosinophil count ≥ 150 cells/mcL and member has experienced ≥ 1 exacerbations requiring one of the following: Oral/systemic corticosteroid treatment, ER visit, hospital admission, or office visit;
   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 Cinqair, Fasenra, Nucala, or Xolair;
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, immunologist, pulmonologist, or otolaryngologist;
3. Age ≥ 18 years;
4. CRSwNP is inadequately controlled by medical therapy with two of the following:
   a. Intranasal corticosteroids (INS) within the past year;
   b. Systemic corticosteroid therapy (SCS);
   c. Nasal nebulized solution of budesonide;
   d. Contraindication or intolerance to SCS;
5. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Xolair;
6. Prior nasal surgery will be taken into consideration;

7. Dose does not exceed 300 mg every other week.

**Approval duration: 6 months**

**D. 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;
3. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Xolair;
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.

**Approval duration: 12 months**

**B. Asthma** (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 (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);
3. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Xolair;
4. 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. 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 nasal polyp size, reduced need for systemic corticosteroids, improved sense of smell, improved quality of life);
3. Dupixent is not prescribed concurrently with Cinqair, Fasenra, Nucala, or Xolair;
4. If request is for a dose increase, new dose does not exceed 300 mg every other week.

**Approval duration: 12 months**

**D. 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
FDA: Food and Drug Administration
GINA: Global Initiative for Asthma
ICS: inhaled corticosteroid
LABA: long-acting beta$_2$ 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 | | |
| 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 acetonide 0.05% (Lidex®, Lidex E®) cream, ointment, gel, solution | | |
| triamcinolone acetonide 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 acetonide 0.025% (Synalar®) cream, ointment | | |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| mometasone 0.1% (Elocon®) cream, ointment, lotion | | |
| triamcinolone acetonide 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 acetonide 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 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<br>40 mcg, 80 mcg per actuation<br>1-4 actuations BID | 4 actuations BID |
| budesonide (Pulmicort®) | > 400 mcg/day<br>90 mcg, 180 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Alvesco® (ciclesonide) | > 160 mcg/day<br>80 mcg, 160 mcg per actuation<br>1-2 actuations BID | 2 actuations BID |
| Aerospan® (flunisolide) | > 320 mcg/day<br>80 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |
| Flovent® (fluticasone propionate) | > 250 mcg/day<br>44-250 mcg per actuation<br>2-4 actuations BID | 2 actuations BID |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| Arnuity Ellipta® (fluticasone furoate) | 200 mcg/day<br>100 mcg, 200 mcg per actuation<br>1 actuation QD | 1 actuation QD |
| Asmanex® (mometasone) | >220 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 |
| Advair® (fluticasone/ salmeterol) | 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 |
| Symbicort® (budesonide/ formoterol) | 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 |
| 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 |

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| 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 |

*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 (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 | *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 |
| 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 | See regimen |

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| | 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 100 mg SC every other week or 300 mg 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 | |
| CRSwNP | 300 mg SC every other week | 300 mg every other 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 6-11 years of age.*

## VII. References

1. Dupixent Prescribing Information. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.; October 2021. Available at: www.dupixent.com. Accessed November 1, 2021.
2. DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed November 15, 2021.
3. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. New England Journal of Medicine. 2016; 375: 2335-48.
4. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dematitis. *J Am Acad Dermatol*. 2014 February; 70(2): 338–351.
5. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020 Dec;34(12):2717-2744.
6. Leshem YA, Hajar T, Hanifin JM, et al. What the Eczema Area and Severity Index score tells us about the severity of atopic dermatitis: an interpretability study. British Journal of Dermatology 2015; 172(5):1353-1357.

7. National Asthma Education and Prevention Program: Expert panel report III: Guidelines for the diagnosis and management of asthma. Bethesda, MD: National Heart, Lung, and Blood Institute, 2007. (NIH publication no. 08-4051). Available at http://www.nhlbi.nih.gov/health-pro/guidelines/current/asthma-guidelines. Accessed November 15, 2021.
8. National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group: 2020 Focused Updates to the Asthma Management Guidelines. Bethesda, MD: National Heart, Lung, and Blood Institute, 2020. Available at https://www.nhlbi.nih.gov/health-topics/asthma-management-guidelines-2020-updates. Accessed November 15, 2021.
9. Global Initiative for Asthma. Global strategy for asthma management and prevention (2021 report). Available from: www.ginasthma.org. Accessed November 15, 2021.
10. Global Initiative for Asthma. Difficult-to-treat and severe asthma in adolescent and adult patients – diagnosis and management, v3.0 April 2021. Available at: www.ginasthma.org. Accessed November 15, 2021.
11. Rosenfeld RM, Piccirillo JF, Chandrasekhar SS, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngology–Head and Neck Surgery 2015, Vol. 152(2S) S1–S39.
12. Peters AT, Spector S, Hsu J, et al. Diagnosis and management of rhinosinusitis: a practice parameter update. Ann Allergy Asthma Immunol 2014. 113:347-85.
13. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. doi: 10.1111/all.13875.
14. Han JK, Bosson JV, Cho SH, et al. Multidisciplinary consensus on a stepwise treatment algorithm for management of chronic rhinosinusitis with nasal polyps. Int Forum Allergy Rhinol. 2021;1-10. Available at: https://onlinelibrary.wiley.com/doi/10.1002/alr.22851. Accessed June 16, 2021.

**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 |

**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.