AETNA BETTER HEALTH®
Coverage Policy/Guideline

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| Name: | Dupixent | Page: | 1 of 11 |
| Effective Date: | 4/15/2024 | Last Review Date: | 3/8/2024 |

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|---|---|---|---|
| Applies to: | ☐Illinois | ☐Florida | ☐New Jersey |
| | ☒Maryland | ☐Michigan | ☒Florida Kids |
| | ☒Pennsylvania Kids | ☐Virginia | ☒Kentucky PRMD |

## Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Dupixent under the patient's prescription drug benefit.

## Description:

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. 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.
B. Dupixent is indicated 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.
C. Dupixent is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).
D. Dupixent is indicated for the treatment of adult and pediatric patients aged 12 years and older, weighing at least 40 kg, with eosinophilic esophagitis (EoE).
E. Dupixent is indicated for the treatment of adult patients with prurigo nodularis (PN).

Compendial Uses
Immune checkpoint inhibitor-related toxicities

*Limitation of Use: Dupixent is not indicated for the relief of acute bronchospasm or status asthmaticus*

All other indications are considered experimental/investigational and not medically necessary.

## Applicable Drug List:

Dupixent

## Policy/Guideline:

**Documentation:**
**Submission of the following information is necessary to initiate the prior authorization review:**
**A. Atopic dermatitis**

1. Initial requests:
   i. Member's chart notes or medical records showing affected area(s) and body surface area (where applicable).
   ii. Member's chart notes, medical record documentation, or claims history of prerequisite therapies including response to therapy. If prerequisite therapies are not advisable, documentation of why therapies are not advisable for the member.
2. Continuation requests: Documentation (e.g., chart notes) that the member has experienced a positive clinical response to therapy as evidenced by low disease activity or improvement in signs or symptoms of atopic dermatitis.

**B. Asthma**

1. Initial requests:
   i. Member's chart or medical record showing pretreatment blood eosinophil count (where applicable).
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried
   including drug, dose, frequency, and duration.
2. Continuation requests: Chart notes or medical record documentation supporting improvement in asthma control.

**C. Chronic rhinosinusitis with nasal polyposis**

1. Initial requests:
   i. Member's chart or medical record showing nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) details (e.g., location, size), or Meltzer Clinical Score or endoscopic nasal polyp score (NPS) (where applicable).
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

**D. Eosinophilic esophagitis**

1. Initial requests:
   i. Member's chart or medical record showing endoscopic biopsy details including intraepithelial esophageal eosinophil count.
   ii. Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.
2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

**E. Prurigo Nodularis**

1. Initial requests:
   i. Member's chart or medical record of symptoms (e.g., pruritus, nodular lesions).

ii. Member's chart, medical record, or claims history of prerequisite therapies including response to therapy. If therapy is not advisable, documentation of clinical reason to avoid therapy.

2. Continuation requests: Chart notes or medical record documentation supporting positive clinical response.

**Prescriber Specialty:**
This medication must be prescribed by or in consultation with ONE of the following:

A. Atopic dermatitis: dermatologist or allergist/immunologist
B. Asthma: allergist/immunologist or pulmonologist
C. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist or otolaryngologist
D. Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
E. Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist, or oncologist
F. Prurigo Nodularis: dermatologist or allergist/immunologist

**Criteria for Initial Approval:**

**A. Atopic dermatitis**

**Authorization of 4 months may be granted for members 6 months of age or older who have previously received a biologic or targeted synthetic drug indicated for moderate-to-severe atopic dermatitis in the past year.**

**Authorization of 4 months may be granted for treatment of moderate-to-severe atopic dermatitis in members 6 months of age or older when ALL the following criteria are met:**

1. Affected body surface is greater than or equal to 10% body surface area OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
2. Member meets one of the following:
   i. Member has had an inadequate treatment response with one of the following in the past year:
      a. A medium potency to super-high potency topical corticosteroid (see Appendix A)
      b. A topical calcineurin inhibitor
   ii. The use of medium potency to super-high potency topical corticosteroid and topical calcineurin inhibitor are not advisable for the member (e.g., due to contraindications, prior intolerances, potency not appropriate for member's age).

**B. Asthma**

**Authorization of 6 months may be granted for members 6 years of age or older who have previously received a biologic drug indicated for asthma.**
**OR**

**Authorization of 6 months may be granted for treatment of asthma in members 6 years of age or older when ALL the following criteria are met:**

1. Member as uncontrolled asthma as demonstrated by experiencing at least one of the following within the past year:
   i. Two or more asthma exacerbations requiring oral or injectable corticosteroid treatment.
   ii. One or more asthma exacerbation resulting in hospitalization or emergency medical care visit.
   iii. Poor symptom control (frequent symptoms or reliever use, activity limited by asthma, night waking due to asthma).
2. Member meets one of the following criteria:
   i. Member has a baseline blood eosinophil count of at least 150 cells per microliter and inadequate asthma control despite current treatment with both of the following medications at optimized doses:
      a. Medium-to-high-dose inhaled corticosteroid
      b. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
   ii. Member has inadequate asthma control despite current treatment with all of the following medications at optimized doses*:
      a. High-dose inhaled corticosteroid
      b. Additional controller (i.e., long acting beta2-agonist, long acting muscarinic antagonist, leukotriene modifier, or sustained-release theophylline)
      c. Oral glucocorticoids (at least 5 mg per day of prednisone/prednisolone or equivalent)
      *Members should be receiving treatment with inhaled corticosteroid and additional controller for at least the previous 3 months, and oral glucocorticoids for most days during the previous 6 months (e.g. 50% of days, 3 steroid bursts in the previous 6 months).[6]
3. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Dupixent.

**C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)**

**Authorization of 6 months may be granted for adult members who have previously received a biologic drug indicated for CRSwNP.**

**OR**

**Authorization of 6 months may be granted for treatment of CRSwNP in members 18 years of age or older when ALL the following criteria are met:**

1. Member has bilateral nasal polyposis and chronic symptoms of sinusitis despite intranasal corticosteroid treatment for at least 2 months unless contraindicated or not tolerated; and
2. The member has CRSwNP despite ONE of the following:
   i. Prior sino-nasal surgery; or
   ii. Prior treatment with systemic corticosteroids within the last two years was ineffective, unless
   contraindicated or not tolerated; and
3. Member has ONE of the following:
   i. A bilateral nasal endoscopy, anterior rhinoscopy, or computed tomography (CT) showing polyps reaching below the lower border of the middle turbinate or beyond in each nostril
   ii. Meltzer Clinical Score of 2 or higher in both nostrils
   iii. A total endoscopic nasal polyp score (NPS) of at least 5 with a minimum score of 2 for each nostril
4. Member has nasal blockage plus ONE additional symptom:
   i. Rhinorrhea (anterior/posterior); or
   ii. Reduction or loss of smell; or
   iii. Facial pain or pressure
5. Member will continue to use a daily intranasal corticosteroid while being treated with Dupixent, unless contraindicated or not tolerated.

**D. Eosinophilic esophagitis (EoE)**

**Authorization of 6 months may be granted for treatment of EoE in members one year of age or older, weighing at least 15 kg, when ALL the following criteria are met:**

1. Member meets EITHER of the following:
   i. Member is 1 year of age to less than 11 years of age and has clinical manifestations of disease (e.g., vomiting, heartburn, abdominal pain, food refusal, failure to thrive).
   ii. Member is 11 years of age or older and has history of an average of at least 2 episodes of dysphagia (with intake of solids) per week.
2. Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field.
3. Member has had an inadequate treatment response to BOTH of the following:
   i. Proton pump inhibitor
   ii. Systemic corticosteroid or local therapies (e.g., budesonide, fluticasone [powder or suspension for inhalation] swallowed), unless contraindicated or not tolerated.

**E. Prurigo Nodularis**

**Authorization of 6 months may be granted for treatment of prurigo nodularis in members 18 years of age or older when ALL the following criteria are met:**

1. Member must have pruritus lasting at least 6 weeks.
2. Member has history or signs of repeated itch-scratch cycle (e.g., scratching, picking, or rubbing).
3. Member must have a minimum of 20 nodular lesions.
4. Member meets ONE of the following:
   i. Member has had an inadequate response to one of the following:
      a. A medium to super-high potency topical corticosteroid (see Appendix A)
      b. A topical calcineurin inhibitor
      c. Phototherapy (e.g., UVB, PUVA)
      d. Pharmacologic treatment with methotrexate or cyclosporine
   ii. Member has had an intolerance or a clinical reason to avoid ANY of the following:
      a. Medium to super-high potency topical corticosteroid (see Appendix A) and topical calcineurin inhibitor
      b. Pharmacologic treatment with methotrexate and cyclosporine (see Appendix B)

**F. Immune checkpoint inhibitor-related toxicity**

**Authorization of six month may be granted for treatment of immune checkpoint inhibitor-related toxicity when member has a refractory case of immune-therapy related severe (G3) pruritus**.

**Continuation of Therapy:**

**A. Atopic dermatitis**

Authorization of 12 months may be granted for members 6 months of age or older (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis when the member has achieved or maintained a positive clinical response as evidenced by low disease activity (i.e., clear or almost clear skin), or improvement in signs and symptoms of atopic dermatitis (e.g., redness, itching, oozing/crusting).

**B. Asthma**

Authorization of 12 months may be granted for continuation of treatment of asthma in members 6 years of age or older when ALL the following criteria are met:

1. Asthma control has improved on Dupixent treatment as demonstrated by at least ONE of the following:
   i. A reduction in the frequency and/or severity of symptoms and exacerbations
   ii. A reduction in the daily maintenance oral corticosteroid dose

2. Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with Dupixent.

**C. Chronic rhinosinusitis with nasal polyposis (CRSwNP)**

Authorization of 12 months may be granted for continuation of treatment of chronic rhinosinusitis with nasal polyposis when ALL the following are met:

1. Member is 18 years of age or older.
2. Member has achieved or maintained positive clinical response to Dupixent therapy as evidenced by improvement in signs and symptoms of CRSwNP (e.g., improvement in nasal congestion, nasal polyp size, loss of smell, anterior or posterior rhinorrhea, sinonasal inflammation, hyposmia and/or facial pressure or pain or reduction in corticosteroid use).
3. Member will continue to use a daily intranasal corticosteroid while being treated with the requested medication, unless contraindicated or not tolerated.

**D. Eosinophilic Esophagitis**

Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members 12 years of age or older, weighing at least 40 kg, when member has achieved or maintained a positive clinical response with Dupixent therapy as evidenced by improvement in signs and symptoms of eosinophilic esophagitis (e.g., dysphagia, heartburn, chest pain, emesis).

**E. Prurigo Nodularis**

Authorization of 12 months may be granted for members 18 years of age or older (including new members) who are using the requested medication for prurigo nodularis when the member has achieved or maintained a positive clinical response as evidenced by ONE of the following:

1. Low disease activity (i.e., clear, or almost clear skin).
2. Reduction in pruritis intensity and improvement in extent and severity of nodular lesions.

**F. Immune checkpoint inhibitor-related toxicity**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

**Other:**

**For all indications**: Member cannot use Dupixent concomitantly with any other biologic drug or targeted synthetic drug for the same indication.

Note: If the member is a current smoker or vaper, they should be counseled on the harmful effects of smoking and vaping on pulmonary conditions and available smoking and vaping cessation options.

**Appendices:**

**Appendix A: Table. Relative potency of select topical corticosteroid products**

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| I. Super-high potency (group 1) | Augmented betamethasone dipropionate | Ointment, Lotion, Gel | 0.05% |
| | Clobetasol propionate | Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray | 0.05% |
| | Fluocinonide | Cream | 0.1% |
| | Flurandrenolide | Tape | 4 mcg/cm$^2$ |
| | Halobetasol propionate | Cream, Lotion, Ointment, Foam | 0.05% |
| II. High potency (group 2) | Amcinonide | Ointment | 0.1% |
| | Augmented betamethasone dipropionate | Cream | 0.05% |
| | Betamethasone dipropionate | Ointment | 0.05% |
| | Clobetasol propionate | Cream | 0.025% |
| | Desoximetasone | Cream, Ointment, Spray | 0.25% |
| | | Gel | 0.05% |
| | Diflorasone diacetate | Ointment, Cream (emollient) | 0.05% |
| | Fluocinonide | Cream, Ointment, Gel, Solution | 0.05% |
| | Halcinonide | Cream, Ointment | 0.1% |
| | Halobetasol propionate | Lotion | 0.01% |
| **Potency** | **Drug** | **Dosage form** | **Strength** |
| III. High potency (group 3) | Amcinonide | Cream, Lotion | 0.1% |
| | Betamethasone dipropionate | Cream, hydrophilic emollient | 0.05% |
| | Betamethasone valerate | Ointment | 0.1% |
| | | Foam | 0.12% |
| | Desoximetasone | Cream, Ointment | 0.05% |
| | Diflorasone diacetate | Cream | 0.05% |
| | Fluocinonide | Cream, aqueous emollient | 0.05% |
| | Fluticasone propionate | Ointment | 0.005% |
| | Mometasone furoate | Ointment | 0.1% |
| | Triamcinolone acetonide | Cream, Ointment | 0.5% |
| IV. Medium potency (group 4) | Betamethasone dipropionate | Spray | 0.05% |
| | Clocortolone pivalate | Cream | 0.1% |
| | Fluocinolone acetonide | Ointment | 0.025% |
| | Flurandrenolide | Ointment | 0.05% |
| | Hydrocortisone valerate | Ointment | 0.2% |
| | Mometasone furoate | Cream, Lotion, Solution | 0.1% |
| | Triamcinolone acetonide | Cream | 0.1% |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| | | Ointment | 0.05% and 0.1% |
| | | Aerosol Spray | 0.2 mg per 2-second spray |
| V. Lower-mid potency (group 5) | Betamethasone dipropionate | Lotion | 0.05% |
| | Betamethasone valerate | Cream | 0.1% |
| | Desonide | Ointment, Gel | 0.05% |
| | Fluocinolone acetonide | Cream | 0.025% |
| | Flurandrenolide | Cream, Lotion | 0.05% |
| | Fluticasone propionate | Cream, Lotion | 0.05% |
| | Hydrocortisone butyrate | Cream, Lotion, Ointment, Solution | 0.1% |
| | Hydrocortisone probutate | Cream | 0.1% |
| | Hydrocortisone valerate | Cream | 0.2% |
| | Prednicarbate | Cream (emollient), Ointment | 0.1% |
| | Triamcinolone acetonide | Lotion | 0.1% |
| | | Ointment | 0.025% |
| VI. Low potency (group 6) | Alclometasone dipropionate | Cream, Ointment | 0.05% |
| | Betamethasone valerate | Lotion | 0.1% |
| | Desonide | Cream, Lotion, Foam | 0.05% |
| | Fluocinolone acetonide | Cream, Solution, Shampoo, Oil | 0.01% |
| | Triamcinolone acetonide | Cream, lotion | 0.025% |
| VII. Least potent (group 7) | Hydrocortisone (base, greater than or equal to 2%) | Cream, Ointment, Solution | 2.5% |
| | | Lotion | 2% |
| | Hydrocortisone (base, less than 2%) | Cream, Ointment, Gel, Lotion, Spray, Solution | 1% |
| | | Cream, Ointment | 0.5% |
| | Hydrocortisone acetate | Cream | 2.5% |
| | | Lotion | 2% |
| | | Cream | 1% |

**Appendix B: Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate or Cyclosporine**

1. Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
2. Drug interaction
3. Risk of treatment-related toxicity
4. Pregnancy or currently planning pregnancy

5. Breastfeeding
6. Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
7. Hypersensitivity
8. History of intolerance or adverse event

## Approval Duration and Quantity Restrictions:

**Approval:**

- Initial: atopic dermatitis = 4 months; all others = 6 months
- Renewal: 12 months

**Quantity Level Limit:**

| | |
|---|---|
| Dupixent 200 mg / 1.14 mL pre-filled syringe / pen: | 2 syringes/pens per 28 days |
| Dupixent 300 mg / 2 mL prefilled syringe/pen: | 4 syringes/pens per 28 days |
| Dupixent 100 mg / 0.67 mL prefilled syringe: | 2 syringes per 28 days |

NOTE: Quantity approved with requests will be based upon FDA-approved dosage.

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