| AETNA BETTER HEALTH®<br>Coverage Policy/Guideline | | | |
|---|---|---|---|
| Name: | Dupixent | Page: | 1 of 10 |
| Effective Date: | 8/19/2024 | Last Review Date: | 7/22/2024 |
| Applies to: | ☒Illinois | | |

## 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 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 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, 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:
   i. Provider attestation 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. Chart notes 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:
   i. Provider attestation supporting improvement in asthma control.

**C. Chronic rhinosinusitis with nasal polyposis**

1. Initial requests:
   i. 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:
   i. Provider attestation supporting positive clinical response.

**D. Eosinophilic esophagitis**

1. Initial requests:
   i. Chart notes or medical record documentation 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:
   i. Chart notes or medical record documentation supporting positive clinical response.

**E. Prurigo Nodularis**

1. Initial requests:
   i. Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
   ii. Chart notes, medical record documentation, 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:

i. 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: Any
B. Asthma: allergist/immunologist or pulmonologist
C. Chronic rhinosinusitis with nasal polyposis: allergist/immunologist, pulmonologist, 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 6 months may be granted for members 6 months of age or older who have previously received a biologic drug indicated for atopic dermatitis.**
**OR**
**Authorization of 6 months may be granted for members 6 months of age or older for treatment of moderate-to-severe atopic dermatitis when ALL the following criteria are met:**

1. Member has an inadequate treatment response with a medium to high potency topical corticosteroid (See Appendix A) in the past year.
2. Member has an inadequate response with ONE of the following in the past 2 years:
   i. Generic immunosuppressant
   ii. Topical Calcineurin Inhibitors (TCI)
   iii. Phototherapy
   iv. Phosphodiesterase-4 inhibitor (PDE-4)

**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 in the past year.**
**OR**
**Authorization of 6 months may be granted for members 6 years of age or older for the treatment of asthma when ONE of the following criteria is met:**

1. Member has a baseline blood eosinophil count of at least 150 cells per microliter and 1 exacerbation (OCS burst, ER visit, hospital, office visit).
2. Member has Oral Corticosteroid dependent asthma
3. Member has BOTH:

i. A baseline Forced Expiratory Volume (FEV1) that is less than 80% predicted for adults and less than 90% for adolescents.
ii. Prior drug therapy of either a leukotriene modifier OR med-high or max-tolerated ICS + controller OR max-tolerated ICS/LABA combo

**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 in the past year.**
**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 a confirmed diagnosis of CRSwNP
2. The member has CRSwNP despite nasal surgery.
3. CRSwNP is inadequately controlled by medical therapy with 2 of the following in the past year, unless contraindicated or intolerant to:
    i. Intranasal corticosteroids
    ii. Systemic corticosteroid therapy
    iii. Nasal budesonide nebulized solution

**D. Eosinophilic esophagitis (EoE)**
**Authorization of 6 months may be granted for treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when ALL the following criteria are met:**
1. Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field.
2. Member had a failure, intolerance, or contraindication to BOTH of the following:
    i. Eight weeks of use of a 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 meets ONE of the following:
    i. Member has had an inadequate response to ONE of the following:
        a. A medium to 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 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**

1. Authorization of 6 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the member has a refractory case of immune therapy-related severe (G3) pruritis.

2. Authorization of 12 months may be granted for treatment of immune checkpoint inhibitor-related toxicity when the requested medication will be used as additional therapy for moderate (G2) or severe (G3) bullous dermatitis.

**Continuation of Therapy:**

**A. Atopic dermatitis**

Authorization of 12 months may be granted (including new members) who are using the requested medication for moderate-to-severe atopic dermatitis with provider attestation that 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 when ALL the following criteria are met:

1. Provider attestation that 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. Provider attestation that 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. Provider attestation that member has achieved or maintained positive clinical response to 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).

**D. Eosinophilic Esophagitis**

Authorization of 12 months may be granted for continuation of treatment of eosinophilic esophagitis in members one year of age or older, weighing at least 15 kg, when member has achieved or maintained a positive clinical response with Dupixent therapy 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**

1. All members (including new members) requesting authorization for continuation of therapy for severe (G3) pruritis must meet all initial authorization criteria.

2. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate (G2) or severe (G3) bullous dermatitis and who achieve or maintain a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition.

**Other:**

**<u>For all indications</u>:**

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 |
|---|---|---|---|
| | Augmented betamethasone dipropionate | Ointment, Lotion, Gel | 0.05% |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| I. Super-high potency (group 1) | 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% |
| | | Ointment | 0.05% and 0.1% |
| | | Aerosol Spray | 0.2 mg per 2-second spray |

| Potency | Drug | Dosage form | Strength |
|---|---|---|---|
| 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: 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 pre-filled syringe/pen: 4 syringes/pens per 28 days
- Dupixent 100 mg/ 0.67 mL pre-filled syringe: 2 syringes per 28 days

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

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