AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Dupixent	Page:	1 of 15
Effective Date:	11/21/2024	Last Review Date:	10/2024
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

- 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.
- Add-on maintenance treatment in patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.
- Add-on maintenance treatment in patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).
- Treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).
- Treatment of adult patients with prurigo nodularis (PN).
- Add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Limitations of Use

Not indicated for the relief of acute bronchospasm or status asthmaticus.

Compendial Uses

- Immune checkpoint inhibitor-related toxicities

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:

Atopic dermatitis

Initial requests:

- 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.

Continuation requests:
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.

Asthma

Initial requests:

- Chart notes or medical record documentation showing baseline blood eosinophil count (where applicable).
- Chart notes, medical record documentation, or claims history supporting previous medications tried including drug, dose, frequency, and duration.

Continuation requests:
Provider attestation supporting improvement in asthma control.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Initial requests:

- Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.

Continuation requests:
Provider attestation supporting positive clinical response.

Eosinophilic esophagitis (EoE)

Initial requests:

- Chart notes or medical record documentation showing endoscopic biopsy details including intraepithelial esophageal eosinophil count.

- Chart notes, medical record documentation, or claims history supporting previous medications tried. If therapy is not advisable, documentation of clinical reason to avoid therapy.

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

Prurigo Nodularis (PN)

Initial requests:

- Chart notes or medical record documentation of symptoms (e.g., pruritus, nodular lesions).
- 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.

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

Chronic obstructive pulmonary disease (COPD)

Initial requests:

- Chart notes or medical record documentation demonstrating clinical signs and/or symptoms of COPD.
- 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.
- Chart notes or medical record documentation showing absolute blood eosinophil count prior to initiating therapy with the requested medication.
- Chart notes or medical record documentation of moderate or severe exacerbations within the last year.

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

Prescriber Specialties:

This medication must be prescribed by or in consultation with one of the following:

- Atopic dermatitis: any
- Asthma: allergist/immunologist or pulmonologist

- Chronic rhinosinusitis with nasal polyps: allergist/immunologist or otolaryngologist
- Eosinophilic esophagitis: gastroenterologist or allergist/immunologist
- Prurigo nodularis: dermatologist or allergist/immunologist
- Chronic obstructive pulmonary disease: pulmonologist or allergist/immunologist
- Immune checkpoint inhibitor-related toxicity: dermatologist, hematologist or oncologist

Coverage Criteria:

Atopic dermatitis

Authorization of 6 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.

OR

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

- Member has had an inadequate treatment response with a medium to high potency topical corticosteroid; AND
- Member has an inadequate response with ONE of the following in the past 2 years:
  - Generic immunosuppressant
  - Topical Calcineurin Inhibitors (TCI)
  - Phototherapy
  - Phosphodiesterase-4 inhibitor (PDE-4)

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 treatment of moderate-to-severe asthma in members 6 years of age or older when ONE of the following criteria are met:

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

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

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorization of 6 months may be granted for members 12 years of age or older 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 12 years of age or older when all of the following criteria are met:

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

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 of the following criteria are met:

- Diagnosis has been confirmed by esophageal biopsy as characterized by 15 or more intraepithelial esophageal eosinophils per high power field
- Member had a failure, intolerance, or contraindication to BOTH of the following:
  - Eight weeks of use of a generic proton pump inhibitor (e.g. esomeprazole, lansoprazole, omeprazole, pantoprazole, or rabeprazole)
  - Topical glucocorticoids (fluticasone using MDI without a spacer or budesonide administered as an oral slurry)

Prurigo Nodularis

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

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

Chronic obstructive pulmonary disease (COPD)

Authorization of 12 months may be granted for treatment of COPD in members 18 years of age or older when all of the following criteria are met:

- Diagnosis has been confirmed by spirometry showing forced expiratory volume in one second (FEV_1)/forced vital capacity (FVC) less than 0.7 post-bronchodilation.
- Member demonstrates classic signs or symptoms of COPD (e.g., dyspnea, wheezing, chest tightness, fatigue, activity limitation, cough with or without sputum production, chronic bronchitis).
- Member has an absolute blood eosinophil count of at least 300 cells per microliter prior to initiating therapy with the requested medication.
- Member has inadequately controlled COPD as demonstrated by experiencing either of the following in the last year:
    - At least two moderate exacerbations resulting in treatment with systemic glucocorticoids, antibiotics, or both.
    - One or more severe exacerbation(s) requiring hospitalization or an emergency medical care visit.
- Member meets either of the following:

- Member is currently receiving maintenance inhaled triple therapy (i.e., inhaled corticosteroid [ICS], long-acting muscarinic antagonist [LAMA], and long-acting beta$_2$-agonist [LABA]).
- Member is currently receiving a LAMA and LABA, and has a contraindication to ICS.

- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Immune checkpoint inhibitor-related toxicity

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.

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

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).

Asthma

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

- Asthma control has improved on the requested medication as demonstrated by at least one of the following:
  - A reduction in the frequency or severity of symptoms and exacerbations
  - A reduction in the daily maintenance oral corticosteroid dose
- Member will continue to use maintenance asthma treatments (e.g., inhaled corticosteroid, additional controller) in combination with the requested medication.

Chronic rhinosinusitis with nasal polyps (CRSwNP)

Authorization of 12 months may be granted for continuation of treatment of CRSwNP in members 12 years of age or older when both of the following are met:

- Member has achieved or maintained a positive clinical response with the requested medication 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, sino-nasal inflammation, hyposmia or facial pressure or pain, or reduction in corticosteroid use).

Eosinophilic Esophagitis (EoE)

Authorization of 12 months may be granted for continuation of treatment of EoE in members 1 year of age or older, weighing at least 15 kg, when member has achieved or maintained a positive clinical response with the requested medication as evidenced by improvement in signs and symptoms of EoE (e.g., dysphagia, heartburn, chest pain, emesis).

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 either of the following:

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

Chronic obstructive pulmonary disease (COPD)

Authorization of 12 months may be granted for continuation of treatment of COPD in members 18 years of age or older when both of the following criteria are met:

- Member has achieved or maintained a positive clinical response as evidenced by improvement in signs and symptoms of COPD (e.g., decrease in exacerbations, improvement in pre-bronchodilator FEV_1) or stabilization of disease.
- Member will continue to use maintenance COPD treatments (e.g., ICS with LAMA and LABA, LAMA and LABA) in combination with the requested medication.

Immune checkpoint inhibitor-related toxicities

All members (including new members) requesting authorization for continuation of therapy for severe (G3) pruritis must meet all requirements in the coverage criteria section.

1. 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

For all indications: Member cannot use the requested medication 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.

Appendix

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

Potency	Drug	Dosage form	Strength
Super-high potency (Group 1)	Augmented betamethasone dipropionate	Ointment, Lotion, Gel	0.05%
Super-high potency (Group 1)	Clobetasol propionate	Cream, Gel, Ointment, Solution, Cream (emollient), Lotion, Shampoo, Foam, Spray	0.05%
Super-high potency (Group 1)	Fluocinonide	Cream	0.1%
Super-high potency (Group 1)	Flurandrenolide	Tape	4 mcg/cm^2
Super-high potency (Group 1)	Halobetasol propionate	Cream, Lotion, Ointment, Foam	0.05%
High potency (Group 2)	Amcinonide	Ointment	0.1%

Potency	Drug	Dosage form	Strength
High potency (Group 2)	Augmented betamethasone dipropionate	Cream	0.05%
High potency (Group 2)	Betamethasone dipropionate	Ointment	0.05%
High potency (Group 2)	Clobetasol propionate	Cream	0.025%
High potency (Group 2)	Desoximetasone	Cream, Ointment, Spray	0.25%
High potency (Group 2)	Desoximetasone	Gel	0.05%
High potency (Group 2)	Diflorasone diacetate	Ointment, Cream (emollient)	0.05%
High potency (Group 2)	Fluocinonide	Cream, Ointment, Gel, Solution	0.05%
High potency (Group 2)	Halcinonide	Cream, Ointment	0.1%
High potency (Group 2)	Halobetasol propionate	Lotion	0.01%
High potency (Group 3)	Amcinonide	Cream, Lotion	0.1%
High potency (Group 3)	Betamethasone dipropionate	Cream, hydrophilic emollient	0.05%
High potency (Group 3)	Betamethasone valerate	Ointment	0.1%
High potency (Group 3)	Betamethasone valerate	Foam	0.12%
High potency (Group 3)	Desoximetasone	Cream, Ointment	0.05%
High potency (Group 3)	Diflorasone diacetate	Cream	0.05%
High potency (Group 3)	Fluocinonide	Cream, aqueous emollient	0.05%
High potency (Group 3)	Fluticasone propionate	Ointment	0.005%
High potency (Group 3)	Mometasone furoate	Ointment	0.1%
High potency (Group 3)	Triamcinolone acetonide	Cream, Ointment	0.5%

Potency	Drug	Dosage form	Strength
Medium potency (Group 4)	Betamethasone dipropionate	Spray	0.05%
Medium potency (Group 4)	Clocortolone pivalate	Cream	0.1%
Medium potency (Group 4)	Fluocinolone acetonide	Ointment	0.025%
Medium potency (Group 4)	Flurandrenolide	Ointment	0.05%
Medium potency (Group 4)	Hydrocortisone valerate	Ointment	0.2%
Medium potency (Group 4)	Mometasone furoate	Cream, Lotion, Solution	0.1%
Medium potency (Group 4)	Triamcinolone acetonide	Cream	0.1%
Medium potency (Group 4)	Triamcinolone acetonide	Ointment	0.05% and 0.1%
Medium potency (Group 4)	Triamcinolone acetonide	Aerosol Spray	0.2 mg per 2-second spray
Lower-mid potency (Group 5)	Betamethasone dipropionate	Lotion	0.05%
Lower-mid potency (Group 5)	Betamethasone valerate	Cream	0.1%
Lower-mid potency (Group 5)	Desonide	Ointment, Gel	0.05%
Lower-mid potency (Group 5)	Fluocinolone acetonide	Cream	0.025%

Potency	Drug	Dosage form	Strength
Lower-mid potency (Group 5)	Flurandrenolide	Cream, Lotion	0.05%
Lower-mid potency (Group 5)	Fluticasone propionate	Cream, Lotion	0.05%
Lower-mid potency (Group 5)	Hydrocortisone butyrate	Cream, Lotion, Ointment, Solution	0.1%
Lower-mid potency (Group 5)	Hydrocortisone probutate	Cream	0.1%
Lower-mid potency (Group 5)	Hydrocortisone valerate	Cream	0.2%
Lower-mid potency (Group 5)	Prednicarbate	Cream (emollient), Ointment	0.1%
Lower-mid potency (Group 5)	Triamcinolone acetonide	Lotion	0.1%
Lower-mid potency (Group 5)	Triamcinolone acetonide	Ointment	0.025%
Low potency (Group 6)	Alclometasone dipropionate	Cream, Ointment	0.05%
Low potency (Group 6)	Betamethasone valerate	Lotion	0.1%
Low potency (Group 6)	Desonide	Cream, Lotion, Foam	0.05%
Low potency (Group 6)	Fluocinolone acetonide	Cream, Solution, Shampoo, Oil	0.01%
Low potency (Group 6)	Triamcinolone acetonide	Cream, lotion	0.025%
Least potent (Group 7)	Hydrocortisone (base, greater than or equal to 2%)	Cream, Ointment, Solution	2.5%

Potency	Drug	Dosage form	Strength
Least potent (Group 7)	Hydrocortisone (base, greater than or equal to 2%)	Lotion	2%
Least potent (Group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment, Gel, Lotion, Spray, Solution	1%
Least potent (Group 7)	Hydrocortisone (base, less than 2%)	Cream, Ointment	0.5%
Least potent (Group 7)	Hydrocortisone acetate	Cream	2.5%
Least potent (Group 7)	Hydrocortisone acetate	Lotion	2%
Least potent (Group 7)	Hydrocortisone acetate	Cream	1%

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

- Clinical diagnosis of alcohol use disorder, alcoholic liver disease or other chronic liver disease
- Drug interaction
- Risk of treatment-related toxicity
- Pregnancy or currently planning pregnancy
- Breastfeeding
- Significant comorbidity prohibits use of systemic agents (e.g., liver or kidney disease, blood dyscrasias, uncontrolled hypertension)
- Hypersensitivity
- 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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