AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Dupixent	Page:	1 of 9
Effective Date:	8/19/2024	Last Review Date:	7/22/2024
Applies to:	☒New Jersey		

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.
    - **Close and review under Dupixent State C21976-A Aetna NJ Medicaid.**
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.
    - **Close and review under Biologics in Severe Asthma C26604-A Aetna NJ Medicaid.**
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

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. Chronic rhinosinusitis with nasal polyposis

1. Initial requests:

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

B. 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.

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

Criteria for Initial Approval:

A. 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 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.

B. 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. 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.

C. 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)

D. 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. 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.

B. 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 as evidenced by improvement in signs and symptoms of eosinophilic esophagitis (e.g., dysphagia, heartburn, chest pain, emesis).

C. 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.

D. 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:

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%

Potency	Drug	Dosage form	Strength
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
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%

Potency	Drug	Dosage form	Strength
	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 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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