

Pharmacy Policy

Dupixent (dupilumab)

Policy Number: 9.118

Revision Number: R2

Version Effective Date: 1/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Dupixent (dupilumab)

The Plan may authorize coverage of the above product for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	Concurrent use of another monoclonal antibody
Required Medical Information	<p>For Moderate to Severe Atopic Dermatitis</p> <ol style="list-style-type: none"> 1. A diagnosis of moderate to severe Atopic Dermatitis; AND 2. Attestation of involvement of at least 10% of body surface area; AND 3. An inadequate response, intolerance, or contraindication to at least one formulary medium to very high potency topical corticosteroid; AND 4. Trial and failure of 2 of the following Preferred topical products required prior to

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	<p>Dupixent;</p> <ol style="list-style-type: none"> a. pimecrolimus b. Protopic c. Tacrolimus; AND <ol style="list-style-type: none"> 5. An inadequate response, intolerance, or contraindication to at least one systemic therapy (ex: azathioprine, cyclosporine or methotrexate); AND 6. The prescriber attests that the member is not using another monoclonal antibody with Dupixent. <p>For Moderate to Severe Asthma with Eosinophilic Type or Corticosteroid-Dependent Asthma</p> <ol style="list-style-type: none"> 1. A diagnosis of one of the following: <ol style="list-style-type: none"> a. Moderate to severe asthma and lab documentation indicating blood eosinophil count greater than or equal to 300 cells/mcL in the past 12 months; OR b. Moderate to severe oral corticosteroid dependent Asthma with at least 6 months of use of oral corticosteroids within the last 12 month period; AND 2. The member is symptomatic with use of combination controller therapy (including at least a high dose of inhaled corticosteroids with either a long-acting beta agonist or leukotriene modifier); AND 3. The source of the allergenic asthma-triggers (if known) has been removed or addressed; AND 4. The prescriber attests that the patient is not using another monoclonal antibody with Dupixent. <p>For Chronic Rhinosinusitis with Nasal Polyps</p> <ol style="list-style-type: none"> 1. A diagnosis of chronic rhinosinusitis with nasal polyps; AND 2. An inadequate response, contraindication, or intolerance to the use of at least a 3 month trial of an intranasal corticosteroid; AND 3. An inadequate response, contraindication, or intolerance to an antihistamine or antileukotriene; AND 4. The prescriber attests that the patient is not using another monoclonal antibody with Dupixent.
Age Restrictions	<p>AD: 6 years of age and older Asthma: 12 years of age and older Chronic rhinosinusitis with nasal polyposis: 18 years and older</p>
Prescriber Restriction	<p>Asthma: prescribed by or in consultation with an allergist, pulmonologist or immunologist Atopic dermatitis: prescribed by or in consultation with a dermatologist, allergist, or immunologist Chronic rhinosinusitis with nasal polyposis: prescribed by or in consultation with an allergist, immunologist, or otolaryngologist</p>
Coverage Duration	<p>Initial and Reauthorization: 12 months</p>
Other criteria	<p>Reauthorization:</p> <ol style="list-style-type: none"> 1. Currently receiving medication via Well Sense benefit or member has previously met

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	initial approval criteria; AND
	2. Clinical condition has improved or stabilized

Applicable Coding:

None

Clinical Background Information and References

1. Arkwright PD, Motala C, Subramanian H, et al. Atopic dermatitis working group of the Allergic Skin Diseases committee of the AAAI. Management of difficult-to-treat atopic dermatitis. J Allergy Clin Immunol Pract. 2013;1(2):142-51.
2. Blauvelt A, Gooderham M, Foley P et al. Long-term management of moderate-to-severe atopic dermatitis (AD) with dupilumab and concomitant topical corticosteroids (TCS): a 1-year, randomized, placebo-controlled phase 3 trial (CHRONOS). Paper presented at the 2017 American Academy of Dermatology Annual meeting. Orlando, FL; 2017 March 4.
3. Dupixent (dupilumab) [prescribing information]. Bridgewater, NJ: Sanofi-aventis U.S. LLC; 2018 October.
4. Eichenfield LF, Tom WL, Berger TG, Krol A, Paller AS, Schwarzenberger K, et al. Guidelines of care for the management of atopic dermatitis: section 2. Management and treatment of atopic dermatitis with topical therapies. J Am Acad Dermatol. 2014 Jul;71(1):116-32.
5. Eichenfield LF, Tom WL, Chamlin SL, Feldman SR, Hanifin JM, Simpson EL, et al. Guidelines of care for the management of atopic dermatitis: section 1. Diagnosis and assessment of atopic dermatitis. J Am Acad Dermatol. 2014 Feb;70(2):338-51.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.181 Dupixent Policy retired, new policy created. Removed 'documentation' language where unnecessary, removed adherence/compliance requirements.	1/1/2021	P&T Committee NH DHHS

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Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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