Washington State Health Care Authority

Atopic Dermatitis Agents: Dupilumab (Dupixent)

Medical policy no. 90.27.30.20 Effective Date: April 1, 2020

Related medical policies:

90.23.00 Atopic Dermatitis Agents – Topical Phosphodiesterase Inhibitors
90.78.40 Atopic Dermatitis Agents – Topical Immunosuppressives
44.60.40 Asthma and COPD Agents – IL-5 Antagonists

Note: New-to-market drugs are non-preferred and subject to this class/category prior authorization (PA) criteria. Non-preferred agents in this class/category, require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class/category documentation of inadequate response to ONE preferred agent is needed.

Background:

Dupilumab (Dupixent) is an interleukin-4 receptor antagonist used in the treatment of moderate to severe atopic dermatitis when conventional therapy is not effective and as add-on maintenance treatment for moderate-to-severe asthma with eosinophilic phenotype or oral corticosteroid (OCS)-dependent asthma.

Drug	Medical Necessity
Dupilumab (Dupixent)	Dupilumab may be considered medically necessary when used in patients 12 years of age or older: • for the treatment of severe atopic dermatitis when their disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable; OR • as an add-on maintenance treatment for moderate-to-severe asthma with an eosinophilic phenotype; OR • as an add-on maintenance treatment for moderate-to-severe oral corticosteroid-dependent asthma • as an add-on maintenance treatment for chronic rhinosinusitis with bilateral nasal polyposis (in patients 18 years of age or older)

Clinical policy:

Clinical Criteria	
Atopic Dermatitis	Dupilumab may be approved when all of the following criteria are met: 1. Diagnosis of severe chronic atopic dermatitis with at least one of the following: a. Percent of body surface area (BSA) involvement (minimum of at least 10% BSA involvement); **OR** b. Disease severity scale scoring to demonstrate severe chronic atopic dermatitis (e.g., Investigator's Global Assessment (IGA) score of 3 or greater; Eczema Area and Severity Index (EASI); etc.); **AND** 2. Clinical documentation of functional impairment due to atopic dermatitis, which may include, but is not limited to: a. documentation of limitation of activities of daily living (ADLs); OR b. skin infections; OR c. sleep disturbances; **AND** 3. History of failure, defined as unable to achieve or maintain remission of low or mild disease; intolerance; contraindication or clinically inappropriate to **ALL** (a, b, and c) of the following: a. **TWO** topical corticosteroids for daily treatment of minimum 14-days each: i. Children and adolescents: Failure of 2 medium potency corticosteroids in the previous 6 months, unless member has contraindication(s) to all preferred topical corticosteroid; **OR** ii. Adults: Failure of 2 high or very high potency corticosteroids in the previous 6 months, unless member has contraindication(s) to all preferred topical corticosteroids; **AND** b. **ONE** topical calcineurin inhibitors for daily treatment for at least 28-days: i. pimecrolimus; **OR** ii. tacrolimus; **AND** c. At least **ONE** of the following: i. Phototherapy; **OR** ii. Any ONE of the following systemic immunosuppressants: 1. methotrexate; **OR** 2. cyclosporine; **OR** 3. azathioprine; **OR** 4. mycophenolate; **AND** 4. Patient is 12 years of age or older; **AND** 5. Prescribed by or in consultation with a specialist in dermatology or allergy. If ALL criteria are met, the request may be approved for 6 months

	Reauthorization Criteria Dupilumab may be reauthorized when all of the following criteria are met: 1. Clinical documentation of disease stability or improvement defined by **BOTH** of the following: a. At least **ONE** of the following: i. reduction in body surface area involvement of at least 20%; **OR** ii. achieved or maintained clear or minimal disease from baseline (equivalent to IGA score of 0 or 1; **OR** iii. experienced or maintained a decrease in Eczema Area and Severity Index (EASI) score of at least 50%; **AND** b. An improvement in functional impairment, which may include but is not limited to: i. improvement in of limitation of activities of daily living (ADLs); **OR** ii. skin infections; **OR** iii. sleep disturbances If ALL criteria are met, the request may be approved for 12 months
Asthma with an eosinophilic phenotype	Dupilumab may be approved when all of the following criteria are met: 1. Documentation of blood eosinophil count (in the absence of other potential causes of eosinophilia) of **ONE** of the following: a. Greater than or equal to (≥) 150 cells/µL in prior 6 weeks; **OR** b. Greater than or equal to (≥) 300 cells/µL in prior 12 months 2. Uncontrolled or inadequately controlled severe asthma is defined by at least **ONE** of the following: a. FEV_1 less than (<) 80% predicted; **OR** b. Two or more bursts of systemic corticosteroids in the previous 12 months; **OR** c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20); **OR** d. frequent (at least twice per year) additional medical treatment such as: treatment with additional oral corticosteroids, emergency department (ED) visits, hospitalizations, or unplanned (sick) office visits; **AND** limitation of activities of daily living (ADLs), nighttime awakening, or dyspnea 3. History of failure (remains symptomatic after 6 weeks), contraindication or intolerance to high-dose inhaled corticosteroid in combination with additional controller(s); **AND** 4. Dupilumab is to be used in combination with additional asthma controller medications; **AND** 5. Dupilumab is not to be used in combination with other monoclonal antibodies a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab]; **OR** b. Anti-IgE therapy [e.g., omalizumab]; **OR**

	c. Anti-interleukin 4 therapy [e.g., dupilumab]; **AND** 6. Patient is 12 years of age or older; **AND** 7. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology If ALL criteria are met, the request may be approved for 6 months **Reauthorization Criteria** Dupilumab may be reauthorized when all of the following criteria are met: 1. Clinical documentation of disease improvement compared to baseline measures (e.g., reduced missed days from work or school, improved FEV_1, ACQ or ACT scores, decrease in burst of systemic corticosteroids, etc.) If ALL criteria are met, the request may be approved for 12 months
Asthma with oral corticosteroid dependent asthma	Dupilumab may be approved when all of the following criteria are met: 1. Uncontrolled or inadequately controlled severe asthma is defined by at least **ONE** of the following: a. FEV_1 less than (<) 80% predicted b. Two or more bursts of systemic corticosteroids in the previous 12 months c. Poor symptom control (e.g., ACQ score consistently greater than 1.5 or ACT score consistently less than 20) 2. Remains symptomatic after 6 weeks with daily oral corticosteroids in addition to high-dose inhaled corticosteroid in combination with additional controller(s); **AND** 3. Dupilumab is to be used in combination with additional asthma controller medications; **AND** 4. Dupilumab is not be used in combination with other monoclonal antibodies (e.g., mepolizumab, reslizumab, benralizumab, omalizumab) for the treatment of asthma; **AND** 5. Patient is 12 years of age or older; **AND** 6. Prescribed by or in consultation with a specialist in allergy, pulmonology, or immunology If ALL criteria are met, the request may be approved for 6 months **Reauthorization Criteria** Dupilumab may be approved when all of the following criteria are met: 1. Reduction in daily oral corticosteroid dosage or usage; **AND** 2. Clinical documentation of disease improvement compared to baseline measures (e.g., reduced missed days from work or school, improved FEV_1, ACQ or ACT scores, decrease in burst of systemic corticosteroids, etc.)

	If ALL criteria are met, the request may be approved for 12 months
Chronic rhinosinusitis with bilateral nasal polyposis	Dupilumab may be approved when all of the following criteria are met: 1. Clinical documentation of chronic rhinosinusitis with bilateral nasal polyposis; **AND** 2. History of persistent symptoms of rhinosinusitis after completion of 2 months of intranasal corticosteroid use; **AND** 3. Continued use of intranasal corticosteroids while using dupilumab; **AND** 4. History of failure, intolerance, or contraindication to short-courses of systemic (oral or injectable) corticosteroids; **AND** 5. Prescribed by or in consultation with an ear, nose, throat specialist or an allergy specialist; **AND** 6. Patient is 18 years of age or older If ALL criteria are met, the request may be approved for 6 months
	Reauthorization Criteria Dupilumab may be reauthorized when all of the following criteria are met: 1. Continued use of intranasal corticosteroids while using dupilumab; **AND** 2. Clinical documentation of disease improvement compared to baseline, defined as a reduction in sinusitis-related symptoms, such as nasal obstruction, nasal discharge, nasal polyp size, facial pain and pressure, etc.) If ALL criteria are met, the request may be approved for 12 months

Dosage and quantity limits

Indication	Dose and Quantity Limits

Atopic Dermatitis	• Initial Authorization
	  ○ Body Weight:
	  ▪ Less than 60 kg: Up to 13 doses of 200 mg injection for 6 months, based on recommended initial dosing of 400 mg (two 200mg injections), followed by 200 mg every other week
	  ▪ 60 kg or greater: Up to 13 doses of 300 mg injections for 6 months, based on recommended initial dose of 600mg (two 300 mg injections), followed by 300 mg every other week
	  ▪
	• Reauthorization
	  ○ Up to 300 mg every other week

Asthma with an eosinophilic phenotype	• Initial Authorization ○ Up to 13 doses of 200 mg or 300 mg injections for 6 months, based on recommended initial dosing of: ▪ 400 mg (two 200 mg injections) followed by 200 mg every other week; **OR** ▪ 600 mg (two 300mg injections), followed by 300 mg every other week • Reauthorization ○ Up to 300 mg every other week
Asthma with oral corticosteroid dependent asthma	• Initial Authorization ○ Up to 13 doses of 300 mg injections for 6 months, based on recommended initial dosing of: ▪ 600 mg (two 300mg injections), followed by 300 mg every other week • Reauthorization ○ Up to 300 mg every other week
Chronic rhinosinusitis with bilateral nasal polyposis	• Initial Authorization ○ Up to 13 doses of 300 mg injections for 6 months, based on recommended dose of 300 mg every other week • Reauthorization ○ Up to 300 mg every other week

References

1. Dupixent [Prescribing Information]. Tarrytown, NY: Sanofi-Aventis and Regeneron; March 2019
2. Dupixent [Prescribing Information]. Tarrytown, NY: Sanofi-Aventis and Regeneron; June 2019

History

Date	Action and Summary of Changes
10/11/2019	Added age criteria to chronic rhinosinusitis with bilateral nasal polyposis section
09/24/2019	General formatting changes
09/12/2019	New indication for chronic rhinosinusitis with bilateral nasal polyposis
07/31/2019	Updated reauthorization criteria
06/24/2019	New indication for asthma with an eosinophilic phenotype and asthma with oral corticosteroid dependent asthma
04/18/2018	New Policy