Washington State Health Care Authority

Atopic Dermatitis Agents: Dupilumab (Dupixent)

Medical policy no. 90.27.30.AA-4 Effective Date: May 1, 2020

Related medical policies:

90.23.00.AA Atopic Dermatitis Agents – Crisaborole (Eucrisa ™)
90.78.40 Atopic Dermatitis Agents – Topical Immunosuppressives
44.60.40 Asthma and COPD Agents – IL-5 Antagonists

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class 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 documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

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. It is also used as an 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: • for the treatment of moderate-to-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; **OR** • as an add-on maintenance treatment for chronic rhinosinusitis with 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 moderate-to-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), Patient Oriented Eczema Measure (POEM); 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 the inability to achieve or maintain remission; intolerance; contraindication or clinically inappropriate to **ALL** (a, b, c and d) of the following: a. Trial of **TWO** topical corticosteroids for daily treatment for a of minimum 28-days each: i. Children and adolescents: Failure of 2 preferred medium potency corticosteroids in the previous 6 months ; **OR** ii. Adults: Failure of 2 preferred high or very high potency corticosteroids in the previous 6 months; **AND** b. Trial of **ONE** topical calcineurin inhibitor for daily treatment for at least 28-days: i. pimecrolimus; **OR** ii. tacrolimus; **AND** c. Trial of crisaborole for daily treatment for at least 28 days d. At least **ONE** of the following: i. Trial and failure of phototherapy; **OR** ii. Trial and failure of systemic steroids; **OR** iii. Any **ONE** of the following systemic immunosuppressants: 1. methotrexate; **OR** 2. cyclosporine; **OR** 3. azathioprine; **OR** 4. mycophenolate; **AND** 4. Patient is 6 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** If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. **Reauthorization Criteria** Dupilumab may be reauthorized when all 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** If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Asthma with an eosinophilic phenotype	Dupilumab may be approved when all 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; **AND** 2. Moderate-to-severe persistent asthma as 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: emergency department (ED) visits, hospitalizations,

	treatment with mechanical ventilation, or unplanned (sick) office visits; **OR** e. 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. History of failure, contraindication or intolerance to the preferred asthma monoclonal antibodies listed on the AHPDL 5. Dupilumab is to be used in combination with additional asthma controller medications; **AND** 6. 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** 7. Patient is 12 years of age or older; **AND** 8. 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 If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.
	Reauthorization Criteria Dupilumab may be reauthorized when all 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 If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Asthma with oral corticosteroid dependent asthma	Dupilumab may be approved when all the following criteria are met: 1. Moderate-to-severe persistent asthma as 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) 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 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** 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 If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration. **Reauthorization Criteria** Dupilumab may be approved when all 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 If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.
Chronic rhinosinusitis with nasal polyposis	Dupilumab may be approved when all the following criteria are met: 1. Clinical documentation of chronic rhinosinusitis with 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 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 If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial authorization duration.
	Reauthorization Criteria Dupilumab may be reauthorized when all 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 If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the reauthorization duration.

Dosage and quantity limits

Indication	Dose and Quantity Limits
Atopic Dermatitis	• <u>Initial Authorization</u> ○ 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 ▪ • <u>Reauthorization</u> ○ 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; January 2021
2. Sidbury R, Davis DM, Cohen DE, Harrod CG, Begolka WS, Eichenfield LF. Guidelines of care for the management of atopic dermatitis. https://www.jaad.org/article/S0190-9622(14)01264-X/fulltext#secsectitle0080. Published August 1, 2014. Accessed May 17, 2021.

History

Date	Action and Summary of Changes
04/18/2018	New Policy
06/24/2019	New indication for asthma with an eosinophilic phenotype and asthma with oral corticosteroid dependent asthma
07/31/2019	Updated reauthorization criteria
09/12/2019	New indication for chronic rhinosinusitis with bilateral nasal polyposis
09/24/2019	General formatting changes
10/11/2019	Added age criteria to chronic rhinosinusitis with bilateral nasal polyposis section
01/13/2020	Removed word adequate and changed to trial and failure of phototherapy. Changed effective date to May 1, 2020.

01/27/2020	General formatting changes and updated footnote date to January 27, 2020
04/23/2021	Annual policy update. Atopic Dermatitis: updated days duration for trial of corticosteroids, added trial of crisaborole to criteria Asthma with eosinophilic phenotype: added criteria of trial/failure to preferred asthma monoclonal antibodies

Washington State Health Care Authority

Dupilumab (Dupixent)

Provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is this request for a continuation of existing therapy? ☐ Yes ☐ No
   If yes, is there clinical documentation of disease stability or improvement from baseline measures?
   ☐ Yes ☐ No

2. What is patient's current weight? _____ kg Date taken:

3. Indicate patient diagnosis:
   ☐ Moderate to Severe chronic atopic dermatitis ☐ Asthma with an eosinophilic phenotype
   ☐ Asthma with oral corticosteroid dependent asthma ☐ Chronic rhinosinustis with bilateral nasal polyposis
   ☐ Other. Specify:

4. Is this prescribed by or in consultation with any of the following (check all that apply):
   ☐ Allergy/ Immunology ☐ Dermatology ☐ Ear, nose, or throat specialist
   ☐ Pulmonology ☐ Other. Specify:

For diagnosis of Atopic Dermatitis, complete the following:

5. Does patient have any of the following: (check all that apply)
   ☐ At least 10% body surface area (BSA) involvement
   ☐ A disease severity scale scoring demonstrating moderate to severe chronic atopic dermatitis (e.g., Investigator's Global Assessment (IGA) score of 3 or greater; Eczema Area and Severity Index (EASI), Patient Oriented Eczema Measure (POEM); etc.)
   ☐ None of the above

6. Does patient have documentation of functional impairment for any of the following? (Check all that apply)
   ☐ Limitation of activities of daily living (ADLs) ☐ Skin infections
   ☐ Sleep disturbances ☐ Other. Specify:

7. Indicate if the patient has a history of failure, intolerance, or contraindication to any of the following (check all that apply):
   ☐ **For children and adolescents:** Two preferred medium potency topical corticosteroids in the previous 6 months
   ☐ **For adults:** Two preferred high or very high potency topical corticosteroids in the previous 6 months
   ☐ Contraindication(s) to all preferred topical corticosteroids.
   ☐ Topical calcineurin inhibitors (i.e., pimecrolimus, tacrolimus) daily treatment for at least 28 days
   ☐ Phototherapy
   ☐ Systemic Immunosuppressants: (i.e., methotrexate, cyclosporine, azathioprine or mycophenolate)
   ☐ Systemic steroids
   ☐ Crisaborole (Eucrisa) daily treatment for at least 28 days

For diagnosis of Asthma, complete the following:

9. Has patient had any of following (check all that apply):
   - ☐ FEV_1 less than (<) 80% predicted
   - ☐ Two or more bursts of systemic corticosteroids in last 12 months
   - ☐ Poor symptom control (ACQ score consistently greater than 1.5 or ACT score consistently less than 20)
   - ☐ Frequent (at least twice per year) additional medical treatment such as: emergency department (ED) visits, hospitalizations, treatment with mechanical ventilation, or unplanned (sick) office visits
   - ☐ Limitation of activities of daily living, nighttime awakening, or dyspnea

10. Will this be used in combination with other monoclonal antibodies (benralizumab, omalizumab, mepolizumab, reslizumab, dupilumab)? ☐ Yes ☐ No

11. Will patient be using in combination with additional asthma controller medications?
    - ☐ Yes, please indicate the medication and duration of use. _____
    - ☐ No, please explain. _____

12. Does the patient have a history (remains symptomatic after 6 weeks), contraindication or intolerance to high-dose inhaled corticosteroid in combination with additional controller? ☐ Yes ☐ No

13. **For diagnosis of Asthma with oral corticosteroid dependent asthma:** Has the patient used oral corticosteroids daily in addition to high-dose inhaled corticosteroid? ☐ Yes ☐ No

14. **For diagnosis of asthma with an eosinophilic phenotype**: What is patient's blood eosinophil count? _____cells/ µL Date taken: _____

For diagnosis of chronic rhinosinusitis with nasal polyposis, complete the following:

15. Is there clinical documentation in the patient's file confirming the diagnosis of chronic rhinosinusitis with nasal polyposis? ☐ Yes ☐ No

16. Does patient have a history of persistent symptoms of rhinosinusitis after completion of 2 months of intranasal corticosteroid use? ☐ Yes ☐ No

17. Is patient continuing to use intranasal corticosteroids while using dupilumab? ☐ Yes ☐ No

18. Does patient have a history of failure, intolerance, or contraindication to short courses of systemic oral corticosteroids? ☐ Yes ☐ No

CHART NOTES ARE REQUIRED WITH THIS REQUEST		
Prescriber signature	Prescriber specialty	Date