Atopic Dermatitis Agents: Dupilumab (Dupixent)

WA.PHAR.41 Effective Date: May 1, 2020

Related medical policies:

WA.PHAR.42 Atopic Dermatitis Agents – Topical Immunosuppressives

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 current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit:
https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare_Washington.pdf

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 in patients who meet the criteria described in the clinical policy below. If all criteria are not met, the clinical reviewer may determine there is a medically necessary need and approve on a case-by-case basis. The clinical reviewer may choose to use the reauthorization criteria when a patient has been previously established on therapy and is new to Apple Health.

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 at **LEAST TWO** of the following groups for a daily treatment minimum of 28-days each:
   a. Group 1: Topical corticosteroids of at least medium/moderate potency
   b. Group 2: Topical calcineurin inhibitors (pimecrolimus or tacrolimus)
   c. Group 3: Topical PDE-4 inhibitors (crisaborole); **AND**
4. Patient is 6 months and older; **AND**
5. Not used in combination with either of the following drugs:
   a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab]; **OR**
   b. Anti-interleukin 13 therapy [e.g., tralokinumab-ldrm]
   c. Anti-IgE therapy [e.g., omalizumab]; **OR**
   d. Janus kinase inhibitors [e.g., upadacitinib, abrocitinib]; **AND**
6. Prescribed by or in consultation with a specialist in dermatology or allergy.

If ALL criteria are met, the request may be approved for **12 months**

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**
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% of predicted; **OR** b. One or more bursts of systemic corticosteroids or oral corticosteroid dependency in the previous 12 months; **OR** c. 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** d. 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 (e.g., ICS, LABA, LTRA, tiotropium, etc.); **AND** 5. Not used in combination with either of the following drugs: a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab]; **OR** b. Anti-IgE therapy [e.g., omalizumab]; **OR** c. Thymic stromal lymphopoietin blockers [e.g., tezepelumab-ekko]; **AND** 6. Patient is 6 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 **12 months** **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
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. One or more bursts of systemic corticosteroids or oral corticosteroid dependency in the previous 12 months; **OR** c. 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** d. Limitation of activities of daily living (ADLs), nighttime awakening, or dyspnea 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 (e.g., ICS, LABA, LTRA, tiotropium, etc.); **AND** 4. Not used in combination with either of the following drugs: a. Anti-interleukin 5 therapy [e.g., mepolizumab, resilizumab, benralizumab]; **OR** b. Anti-IgE therapy [e.g., omalizumab]; **OR** c. Thymic stromal lymphopoietin blockers [e.g., tezepelumab-ekko]; **AND** 5. Patient is 6 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 **12 months** **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**
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. 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]; **AND** 6. Prescribed by or in consultation with an ear, nose, throat specialist or an allergy specialist; **AND** 7. Patient is 18 years of age or older If ALL criteria are met, the request may be approved for **12 months**
	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**

Dosage and quantity limits

Indication	Dose and Quantity Limits
Atopic Dermatitis	**Initial Authorization** For Adults: 600 mg (two 300 mg injections) for initial dose then 300 mg every other week. Pediatric Patients 6 months-5 years old: ○ Body Weight: ▪ *5 to 15 kg*: 200 mg every 4 weeks ▪ *15 to 30 kg*: 300 mg every 4 weeks Pediatric Patients 6-17 years old: ○ Body Weight: ▪ *15 to less than 30 kg*: 600 mg (two 300 mg injections) for initial dose then 300 mg every 4 weeks. ▪ *30 to less than 60 kg*: 400 mg (two 200 mg injections) for initial dose then 200 mg every other week ▪ *60 kg or more*: 600 mg (two 300 mg injections) for initial dose then 300 mg every other week **Reauthorization** For Adults: Up to 300 mg every other week Pediatric Patients 6 months-5 years old:

	○ Body Weight: ▪ *5 to less than 15 kg*: Up to 200 mg every 4 weeks ▪ *15 to less than 30 kg*: Up to 300 mg every 4 weeks Pediatric Patients 6-17 years old: ○ Body Weight: ▪ *15 to less than 30 kg*: Up to 300 mg every 4 weeks. ▪ *30 to less than 60 kg*: Up to 200 mg every other week ▪ *60 kg or more:* Up to 300 mg every other week
Asthma with an eosinophilic phenotype	**Initial Authorization:** For Adults and Pediatric Patients 12 years and older: ○ 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 For Pediatric Patients 6-11 years old: ○ Body Weight: ▪ *15 to less than 30 kg*: 100 mg every other week **OR** 300 mg every four weeks ▪ *30 kg or more:* 200 mg every other week **Reauthorization** For Adults and Pediatric Patients 12 years and older: ○ Up to 300 mg every other week For Pediatric Patients 6-11 years old: ○ Body Weight: ▪ *15 to less than 30 kg*: Up to 100 mg every other week **OR** 300 mg every four weeks ▪ *30 kg or more*: Up to 200 mg every other week
Asthma with oral corticosteroid dependent asthma	**Initial Authorization** For Adults and Pediatric Patients 12 years and older: 600 mg (two 300mg injections), followed by 300 mg every other week For Pediatric Patients 6-11 years old: ○ Body Weight: ▪ *15 to less than 30 kg*: 100 mg every other week **OR** 300 mg every four weeks ▪ *30 kg or more:* 200 mg every other week **Reauthorization** For Adults and Pediatric Patients 12 years and older: ○ Up to 300 mg every other week For Pediatric Patients 6-11 years old: ○ Body Weight:

	▪ *15 to less than 30 kg*: Up to 100 mg every other week **OR** 300 mg every four weeks ▪ *30 kg or more*: Up to 200 mg every other week
Chronic rhinosinusitis with bilateral nasal polyposis	• Initial Authorization ○ 300 mg every other week • Reauthorization ○ Up to 300 mg every other week

References

1. Dupixent [Prescribing Information]. Tarrytown, NY: Sanofi-Aventis and Regeneron; October 2022
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
06/16/2021	Approved by DUR board
01/31/2023	Version 5 Updates: 1. Grammatical update for criteria (OR was changed to AND) 2. Atopic dermatitis criteria: - Age was updated to reflect new expanded age indication (6 months and older) - Updated trial/failure requirements 3. Asthma criteria: - Age was updated to reflect new expanded age indication (6 years and older) - Updated trial/failure requirements

	- Updated criteria for diagnosis of moderate-to-severe persistent asthma 4. Dose and quantity limits were updated to reflect expanded age indication
09/29/2023	<u>Version 5 Updates:</u> 1. Updated medical necessity language 2. Atopic Dermatitis- added not to be used in combination with anti-interleukin 13 therapy or JAK inhibitors 3. Asthma with an eosinophilic phenotype and asthma with oral corticosteroid dependent asthma—added not to be used in combination with thymic stromal lymphopoietin blockers