Clinical Policy Title:	dupilumab
Policy Number:	RxA.594
Drug(s) Applied:	Dupixent®
Original Policy Date:	03/06/2020
Last Review Date:	2/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Atopic Dermatitis (must meet all)**:**

1. Diagnosis of moderate-to-severe atopic dermatitis;
2. Prescribed by or in consultation with a dermatologist, an immunologist or an allergist;
3. Patient has one (1) of the following (a or b):
   a. Involvement of ≥ 10% of the body surface area (BSA);
   b. Scoring atopic dermatitis (SCORAD) of at least 25;
5. Trial and failure, unless contraindicated or clinically significant adverse effects are experienced, to one of the following (a, b, or c):
   a. medium to high potency topical corticosteroid;
   b. pimecrolimus cream or tacrolimus topical ointment
   c. crisaborole (Eucrisa®) ointment;

Approval Duration
Commercial: 6 months
All Lines of Business (except Medicare): 12 months

B. Eosinophilic Asthma (must meet all)**:**

1. Diagnosis of moderate to severe asthma;
2. Baseline (pre-treatment) peripheral blood eosinophil count ≥ 150 cells/mcL;
3. Patient has experienced ≥ 2 exacerbations with in the last 12 months, requiring one of the following (a or b):
   a. Systemic corticosteroid treatment;
   b. Hospital admission;
4. Patient is currently being treated with one of the following, unless there is a contraindication or intolerance (a or b):
   a. Both of the following (i and ii):
      i. High-dose inhaled corticosteroids;
      ii. Controller medication (e.g., long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA));
   b. Max-dosed combination ICS/LABA product;
5. Prescribed by or in consultation with an allergist/immunologist, or a pulmonologist;

Approval Duration
All Lines of Business (except Medicare): 12 months

C. Corticosteroid dependent Asthma (must meet all):
1. Diagnosis of moderate to severe asthma;
2. Patient is currently dependent on oral corticosteroids for the treatment of asthma;
3. Patient is currently being treated with one of the following, unless there is contraindication or intolerance to the following medications (a or b):
   a. Both of the following (i and ii):
      i. High-dose inhaled corticosteroids (e.g., greater than 500 mcg fluticasone propionate equivalent/day);
      ii. Additional asthma controller medication [e.g., leukotriene receptor antagonist (e.g., montelukast), long-acting beta-2 agonist (LABA) (e.g., salmeterol), tiotropium];
   b. One max-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Symbicort (budesonide/formoterol), Breo Ellipta (fluticasone/vilanterol)];
4. Prescribed by or in consultation with an allergist/immunologist, or a pulmonologist;

Approval Duration
All Lines of Business (except Medicare): 12 months

D. Chronic Rhinosinusitis with Nasal Polyposis (must meet all)**:**
1. Diagnosis of CRSwNP;
2. Prescribed by or in consultation with an allergist, an immunologist, or an otolaryngologist;
3. Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone);
4. Used in combination with another agent for CRSwNP;

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Eosinophilic Esophagitis (must meet all)**:**
1. Diagnosis of EoE;
2. Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain);
3. Patient has ≥ 15 intraepithelial eosinophils per high-power field (eos/hpf);
4. Prescribed by or in consultation with an allergist, an immunologist, or a gastroenterologist;
5. Trial and failure of one of the following, unless clinically significant adverse effects are experienced, or both are contraindicated (a or b):
   a. Proton pump inhibitor;
   b. Topical (esophageal) corticosteroid;

Approval Duration
All Lines of Business (except Medicare): 12 months

F. Prurigo Nodularis (must meet all)**:**
1. Diagnosis of Prurigo Nodularis (PN);
2. Prescribed by or in consultation with a dermatologist, an immunologist or an allergist;
3. Trial and failure of any one of the following, unless contraindicated or clinically significant adverse effects are experienced (a , b or c);
   a. Medium to high potency topical corticosteroids;

b. Topical calcineurin inhibitors;
c. Topical capsaicin;

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Atopic Dermatitis and Prurigo Nodularis (must meet all)**:**
1. Patient is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration
All Lines of Business (except Medicare): 12 months

B. Asthma (EA, CDA) (must meet all):
1. Patient is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples;
2. Demonstrated adherence to asthma controller therapy that includes an ICS plus a controller medication, unless there is a contraindication or intolerance;

Approval Duration
All Lines of Business (except Medicare): 12 months

C. Chronic Rhinosinusitis with Nasal Polyposis (must meet all):
1. Patient is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.
2. Demonstrated adherence to an intranasal corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
All Lines of Business (except Medicare): 12 months

D. Eosinophillic Esophagitis (must meet all):
1. Patient is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.
2. Demonstrated adherence to an topical (esophageal) corticosteroid, unless contraindicated or clinically significant adverse effects are experienced;

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two phase 3 trials of dupilumab versus placebo in atopic dermatitis. New England Journal of Medicine. 2016; 375: 2335-48. Available at: https://www.nejm.org/doi/full/10.1056/nejmoa1610020. Accessed August 18, 2023.
2. Eichenfield F, Tom WL, Chamlin SL, et al. Guidelines of Care for the Management of Atopic Dematitis. J Am Acad Dermatol. 2014 February; 70(2): 338–351. Available at: https://pubmed.ncbi.nlm.nih.gov/24290431/. Accessed August 18, 2023.
3. Sanofi. A Randomized, Double Blind, Placebo-Controlled, Multi-Center, Parallel Group Study to Evaluate the Efficacy and Safety of Dupilumab in Patients with Prurigo Nodularis Who Are Inadequately Controlled on Topical Prescription Therapies or When Those Therapies Are Not Advisable. clinicaltrials.gov; 2022. Available at: https://clinicaltrials.gov/ct2/show/NCT04202679. Accessed August 18, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated as “dupilumab.” 2. Lines of business policy applies to all lines of business. 3. Initial approval criteria I.A.3 was updated to 6 years of age or older. 4. Initial and continued approval criteria was updated to add Medicaid approval duration. 5. Continued therapy criteria II.A.1, II.B.1 & II.C.1 was rephrased to “Patient is currently receiving medication that has been authorized by RxAdvance.” 6. References were reviewed and updated.	10/09/2020	12/07/2020
Policy was reviewed: 1. Initial Approval Criteria I.B.3 was updated from “age 12 years of age or older” to “age 6 years of age or older.” 2. Initial Approval Criteria I.B.4 was updated to remove the statement “requiring any of the following despite adherent use of controller therapy…if LABA contraindication/intolerance)”. 3. Initial Approval Criteria I.B.5 was moved to I.B.6; new criteria for I.B.5 reads “Documentation that Patient has been adherent to ICS therapy plus either a LABA or LTRA (i.e chart notes, fill history) for at least 3 months”. 4. Continued Therapy Criteria II.A.1, II.B.1 and II.C.1 were rephrased to "Patient is currently receiving medication that has been authorized by RxAdvance...". 5. References were reviewed and updated.	10/19/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.3: Updated to include new diagnostic criteria Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) and baseline scoring atopic dermatitis (SCORAD) of at least 25. 2. Initial Approval Criteria, I.A.5.a: Updated trial and failure criteria from Any one formulary medium to very high potency topical corticosteroids, each used for ≥ 2 weeks; to Any one medium to high potency topical corticosteroids, each used for ≥ 2 weeks. 3. Continued Therapy Criteria II.A (Atopic dermatitis): Medicaid approval duration updated from 6 months to 12 months.	06/29/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.3.: Updated age criteria	08/31/2022	10/19/2022

from Age ≥ 6 years to Age ≥ 6 months. 2. Initial Approval Criteria, I.D.: Updated to include criteria for new indication 'EoE'. 3. Continued Therapy Approval Criteria II.D.: Updated to include criteria for new indication 'EoE'. 4. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, prurigo nodularis (PN). 2. Continued Therapy Approval Crtieria, II.E: Updated to include approval criteria for indication, prurigo nodularis (PN). 3. References were reviewed and updated.	11/22/2022	01/17/2023
Policy was reviewed: 1. Clinical Policy Title, Lines of Business Policy Applies to: Updated from All line of Business to All lines of business (except Medicare). 2. Initial Approval Criteria, I.A.2: Updated prescriber criteria to include an immunologist; 3. Initial Approval Criteria, I.A.3: Updated diagnostic criteria from Patient has atopic dermatitis involvement estimated to be ≥ 10% of the body surface area (BSA) and baseline scoring atopic dermatitis (SCORAD) of at least 25 to Patient has one (1) of the following (a or b): a. Involvement of ≥ 10% of the body surface area (BSA); b. Scoring atopic dermatitis (SCORAD) of at least 25; 4. Initial Approval Criteria, I.A.5.c: Updated to include new trial and failure criteria trial and failure of Eucrisa or topical JAK; 5. Initial Approval Criteria, I.A.6, I.B.9, I.D.7 and I.E.7: Updated to remove prior concurrent therapy criteria "Dupixent is not prescribed concurrently with Cinqair®, Fasenra®, Nucala®, Tezspire™, or Xolair®." 6. Initial Approval Criteria, I.B: Updated title from Asthma to Eosinophilic Asthma. 7. Initial Approval Criteria, I.B.1: Updated diagnosis criteria from Diagnosis of asthma and one of the following (a or b): a. Absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months;	08/18/2023	08/25/2023

b. Currently receiving maintenance treatment with systemic glucocorticoids and has received treatment for at least 4 weeks; to Diagnosis of moderate to severe asthma. 8. Initial Approval Criteria, I.B.2: Separated prior diagnosis criteria to form an individual criteria and updated it from Absolute blood eosinophil count ≥ 150 cells/mcL within the past 3 months to Baseline (pre-treatment) peripheral blood eosinophil count ≥ 150 cells/mcL. 9. Initial Approval Criteria, I.B.5: Updated trial and failure criteria from Patient has experienced ≥ 2 exacerbations with in the last 12 months, requiring any of the following: a. Oral/systemic corticosteroid treatment (or increase in dose if already on oral corticosteroid); b. Urgent care visit or hospital admission; c. Intubation to Patient meets one of the following (a or b): a. Patient has experienced ≥ 2 exacerbations requiring systemic corticosteroids (e.g., prednisone) with in the last 12 months; b. Prior asthma-related hospitalization within the past 12 months; 10. Initial Approval Criteria, I.B.7: Updated to remove prior documentation criteria "Documentation that Patient has been adherent to ICS therapy plus either a LABA or LTRA (i.e., chart notes, fill history) for at least 3 months." 11. Initial Approval Criteria, I.B.8: Updated to remove prior concomitant therapy criteria "Dupixent® is prescribed concomitantly with a medium- to high-dose inhaled corticosteroid (ICS) plus either a long-acting beta-2 agonist (LABA) or leukotriene modifier (LTRA)." 12. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Corticosteroid dependent Asthma. 13. Initial Approval Criteria, I.D.1: Updated diagnosis criteria to remove "with documentation of all of the following (a, b, and c): a. Presence of nasal polyps; b. Disease is bilateral; c. Patient has experienced signs and symptoms (e.g., nasal congestion/blockage/obstruction, loss of smell, rhinorrhoea) for ≥ 12 weeks."		

14. Initial Approval Criteria, I.D.4: Updated to include new trial and failure criteria Unless contraindicated, the patient has had an inadequate response to 2 months of treatment with an intranasal corticosteroid (e.g., fluticasone, mometasone).
15. Initial Approval Criteria, I.D.5: Updated to include new combination criteria Used in combination with another agent for CRSwNP.
16. Initial Approval Criteria, I.D and I.E: Updated approval duration from 6 months to 12 months for Commercial.
17. Initial Approval Criteria, I.E.2: Updated to include new criteria pertaining to indication EoE, Patient has symptoms of esophageal dysfunction (e.g., dysphagia, food impaction, gastroesophageal reflux disease [GERD]/heartburn symptoms, chest pain, abdominal pain).
18. Initial Approval Criteria, I.E.5: Updated to remove prior criteria pertaining to indication EoE "Patient does not have hypereosinophilic syndrome or eosinophilic granulomatosis with polyangiitis (Churg-Strauss syndrome)."
19. Initial Approval Criteria, I.E.7.b: Updated prior trial and failure criteria from Corticosteroid to Topical (esophageal) Corticosteroid.
20. Initial Approval Criteria, I.F.1: Updated diagnosis criteria from Diagnosis of Prurigo Nodularis (PN) by a dermatologist for at least 3 months to Diagnosis of Prurigo Nodularis.
21. Initial Approval Criteria, I.F.2: Updated prescriber criteria to include an immunologist or an allergist.
22. Initial Approval Criteria, I.F.4: Updated to remove prior diagnostic criteria "Patient has severe or very severe itch (WI-NRS score ≥ 7) reported within the past week."
23. Initial Approval Criteria, I.F.4: Updated trial and failure criteria from Trial and failure of 2-week course of medium-to-superpotent topical corticosteroids (TCS), unless contraindicated or clinically significant adverse effects are experienced to Trial and failure of any one of the following, unless contraindicated or clinically significant adverse effects are experienced (a , b or c);
    a. Medium to high potency topical corticosteroids;
    b. Topical calcineurin inhibitors;

c. Topical capsaicin; 24. Initial Approval Criteria, I.F.5: Updated to remove prior disease criteria "Patient has at least 20 PN lesions in total on both legs and/or both arms and/or trunk." 25. Continued Therapy Criteria, II.A.1, II.B.1,II.C.1, II.D.1, II.E.1 updated to Patient is currently receiving medication, excluding manufacturer samples. 26. Continued Therapy Approval Criteria, II.A.3, II.C.4, II.D.4: Updated to remove prior concurrent therapy criteria "Dupixent is not prescribed concurrently with Cinqair®, Fasenra®, Nucala®, Tezspire™, or Xolair®." 27. Continued Therapy Approval Criteria, II.A, II.B, II.C, II.D: Updated approval duration from 6 months to 12 months for Commercial. 28. Continued Therapy Approval Criteria, II.B.2: Updated to remove prior therapy adherence criteria "Demonstrated adherence to asthma controller therapy that includes an ICS plus either a LABA or LTRA (if LABA contraindication/intolerance)." 29. Continued Therapy Approval Criteria, II.B.2: Updated to include new therapy criteria Patient continues to be treated with an inhaled corticosteroid (ICS) (e.g., fluticasone, budesonide) with or without additional asthma controller medication (e.g., leukotriene receptor antagonist [e.g., montelukast], long-acting beta-2 agonist [LABA] [e.g., salmeterol], tiotropium) unless there is a contraindication or intolerance to these medications. 30. Continued Therapy Approval Criteria, II.E: Updated approval duration from 6 months to 12 months for Commercial and Medicaid. 31. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy updated: 1. Updated continuation of treatment 2. T/F update for Atopic dermatitis	2/1/2024	2/28/2024