JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS101
		Effective Date	04/19/2017
		Review Date	10/18/2023
	Subject **Dupixent**	*Revision Date*	10/18/2023
		Page	1 of 6

This document applies to the following Participating Organizations:

Priority Partners

Keywords: dupixent

Table of Contents		Page Number
I.	**POLICY**	**1**
II.	**POLICY CRITERIA**	**1**
	A. Dupixent	**1**
III.	**AUTHORIZATION PERIOD/LIMITATIONS**	**3**
IV.	**EXCLUSIONS**	**4**
V.	**RECOMMENDED DOSE**	**4**
VI.	**REFERENCES**	**4**
VII.	**APPROVALS**	**5**

I. POLICY

Dupixent (dupilumab) will require prior authorization to ensure it is used only when clinically appropriate. The process for initiating a prior authorization request can be found in policy PHARM 20.

1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Dupixent** may be approved for the following:

1. **Moderate-to-Severe Atopic Dermatitis**
   a. Patient is 6 months of age or older
   b. Patient has a confirmed diagnosis of moderate to severe chronic atopic dermatitis with documented BSA coverage of 10% or greater.
   c. Patient has documented functional impairment as a result of chronic atopic dermatitis, which can include limitation of activities of daily living (ex. consistent sleep disturbances, problems wearing clothing, skin infections, etc.)
   d. Documentation has been provided showing a baseline assessment using one of the following tools:
      I. Investigator's Static Global Assessment (ISGA) score
      II. Eczema Area and Severity Index (EASI)
      III. Patient-Oriented Eczema Measure (POEM)
      IV. Scoring Atopic Dermatitis (SCORAD) index
   e. Patient has a documented history of treatment failure, contraindication, or intolerance to both of the following formulary topical alternatives:
      I. Two medium to very-high potency topical corticosteroids
      II. One topical calcineurin inhibitor [ex. Elidel (pimecrolimus) or Protopic (tacrolimus)]
      III. Caveat for patients with moderate disease:

i. In addition to trials of topical corticosteroids and a calcinuerin inhibitor, documentation of trial and inadequate response to Eucrisa (crisaborole) is required.

f. Patient has had trial and inadequate response to phototherapy, unless such use is not advised (i.e. patient has a history of skin cancer history, currently taking medication that may be photosensitizing, etc.)
   I. Caveat for pediatric patients: A trial of phototherapy is not required for pediatric patients.

g. Patient has had trial and inadequate response to at least one of the following systemic agents traditionally used for refractory disease, or has a contraindication to systemic therapy:
   I. cyclosporine
   II. methotrexate
   III. mycophenolate mofetil
   IV. azathioprine
   V. Caveat for pediatric patients: A systemic agent trial is not required for pediatric patients.

h. Patient is not being concomitantly treated with other biologics (Enbrel, Xolair, Rituxan, Adbry etc.), or JAK inhibitors (Cibinqo, Rinvoq, etc.) that are indicated for treatment of atopic dermatitis

i. Prescriber is one of the following specialists: allergist, dermatologist, or immunologist

2. **Add-on maintenance treatment of Moderate-to-Severe Asthma with an eosinophilic phenotype**
   a. Patient is 6 years of age or older
   b. Blood eosinophil count of at least 300 cells/microliter in the past 12 months
   c. Documentation has been submitted showing poorly controlled asthma as evidenced by two or more exacerbations in the past 12 months despite the use of high-dose ICS:
      I. For ages 12-17, ICS dose must be 440µg/day or greater of fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the mid-strength approved maintenance dose of ICS-LABA combinations
      II. For 18 years of age and older, ICS dose must be 880 mcg/day or greater of fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the highest approved maintenance dose of ICS-LABA combinations
   d. Documented treatment with at least 2 other controllers in addition to a ICS or ICS-LABA combination (i.e., long-acting beta agonist [if not already using a ICS-LABA combination], an asthma-indicated long-acting anticholinergic agent, leukotriene modifier, or theophylline), for at least 6 months, and demonstrated adherence of 80% or greater; or if patient has a documented allergy, contraindication, or an intolerance to any specified prerequisite agent
   e. Prescriber is one of the following specialists: allergist, immunologist, or pulmonologist

3. **Add-on maintenance treatment of Moderate-to-Severe Oral Corticosteroid-dependent Asthma**
   a. Patient is 6 years of age or older
   b. Documentation has been submitted showing the use of daily oral corticosteroid for at least one month within the last 3 months
   c. Documentation has been submitted showing poorly controlled asthma as evidenced by two or more exacerbations in the past 12 months despite the use of high-dose ICS:
      I. For ages 12-17, ICS dose must be 440µg/day or greater of fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the mid-strength approved maintenance dose of ICS-LABA combinations
      II. For 18 years of age and older, ICS dose must be 880 mcg/day or greater of fluticasone propionate (FP) (ex-actuator) or equivalent daily, or the highest approved maintenance dose of ICS-LABA combinations
   d. Documented treatment with at least 2 other controllers in addition to a ICS or ICS-LABA combination (i.e., long-acting beta agonist [if not already using a ICS-LABA combination], an asthma-indicated long-acting anticholinergic agent, leukotriene modifier, or theophylline), for at least 6 months, and demonstrated adherence

of 80% or greater; or if patient has a documented allergy, contraindication, or an intolerance to any specified prerequisite agent

e. Prescriber is one of the following specialists: allergist, immunologist, or pulmonologist

4. **Add-on maintenance treatment of chronic Rhinosinusitis with Nasal Polyposis (CRSwNP)**
   a. Patient is 18 years of age or older
   b. Patient has a confirmed diagnosis of inadequately controlled CRSwNP and any of the following: nasal congestion and discharge, breathing difficulties, reduced or loss sense of smell and taste, or facial pressure
   c. Documentation showing ONE of the following:
      I. Patient continues to have symptoms after sino-nasal surgery
      II. Patient has had trial and inadequate response to one oral corticosteroid and one nasal corticosteroid regimen
5. **Eosinophilic Esophagitis (EoE)**
   a. Patient is 12 years of age or older, and weighs at least 40 kg (88 lbs.)
   b. Patient has a confirmed diagnosis of of EoE supported by endoscopic biopsy
   c. Documentation showing the following:
      I. Baseline esophageal endoscopic biopsies showing eosinophil-predominant inflammation, evidenced by ≥15 intraepithelial eosinophils per high-power field
      II. Baseline Dysphagia Symptom Questionnaire (DSQ) score to support severity of disease
      III. Patient history of an average of at least 2 episodes of dysphagia with solid foods per week
      IV. Patient has had trial and inadequate response to at least one first-line treatment agent (proton pump inhibitors [PPIs] or topical glucocorticoids)
   d. Prescriber is one of the following specialists: allergist or gastroenterologist
6. **Prurigo Nodularis** (PN)
   a. Patient is 18 years of age or older
   b. Patient has a confirmed diagnosis of PN supported by documentation showing both of the following:
      I. Patients has an average worst itch score of ≥7 on the Worst Itch-Numeric Rating Scale (WI-NRS)
      II. Patient has greater than or equal to 20 nodular lesions
   c. Documentation has been submitted showing trial and inadequate response, or contraindication to both of the following:
      I. two or more medium-to-superpotent topical corticosteroids
      II. topical emollients
   d. Prescriber is a dermatologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval for Dupixent will be restricted to 6 months of therapy
B. Approval for continuation of therapy may be extended in 12-month intervals with documentation of positive clinical response to therapy.
   1. For asthma, specific documentation may consist of ONE of the following:
      a. Reduction in asthma symptoms (wheezing, coughing, shortness of breath, chest tightness)
      b. Reduction in administration frequency of short-acting rescue medication
      c. Reduction in exacerbation frequency and asthma-related hospitalizations (no increase in inhaled or oral corticosteroid dose)
      d. Elevation in predicted FEV1 from the patient's baseline before treatment
   2. For Chronic rhinosinusitis with nasal polyposis, specific documentation may consist of ONE of the following:

a. Reduction in the use of systemic or nasal corticosteroids

3. For atopic dermatitis, specific documentation may consist of a score reduction using ONE of the following clinical evaluation tools:
   a. ISGA: decrease from baseline by at least 2 points
   b. EASI: decrease from baseline by at least 75%
   c. POEM: decrease from baseline by at least 3 points
   d. SCORAD: decrease from baseline by at least 50%
4. For eosinophilic esophagitis, specific documentation may consist of ONE of the following:
   a. Reduction in esophageal intraepithelial eosinophil count to ≤6 eosinophils per high-power field (eos/hpf)
   b. Reduction in DSQ score from baseline
5. For Prurigo nodularis, specific documentation may consist of ONE of the following evaluation tools:
   a. WI-NRS: decrease from baseline by at least 4 points
   b. Investigator's Global Assessment for Prurigo Nodularis-Stage (IGA PN-S): reduction in nodules reflected in a score of 0 or 1 (equivalent of 0-5 nodules)

IV. EXCLUSIONS

A. Dupixent will not be approved for the following:
   1. Patients below the ages indicated for each of the covered diagnoses
   2. Experimental or investigative uses including, but not limited to, the following indications that are not FDA-approved:
      a. Contact dermatitis
      b. Seborrheic dermatitis
      c. Lichen planus
      d. Lichen sclerosis
      e. Psoriasis
      f. Rosacea
      g. Acne Vulgaris
   3. Concurrent use with another biologic product

B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. RECOMMENDED DOSE

Please refer to the FDA-approved prescribing information for indication-specific dosing details.

VI. REFERENCES

1. Dupixent [prescribing information]. Tarrytown, NY: Regeneron Pharmaceuticals Inc; September 2022
2. Eichenfield LF, Tom WL, Berger TG, et.al. Guidelines of care for the management of atopic dermatitis: Section 1. Diagnosis and Assessment of Atopic Dermatitis. J Am Acad Dermatol. 2014;70:338-51.
3. Eichenfield LF, Tom WL, Berger TG, 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;71(1):116.
4. Sidbury R, Davis DM, Cohen DE, et. al. Guidelines of care for the management of atopic dermatitis: section 3. Management and treatment with phototherapy and systemic agents. J Am Acad Dermatol 2014 Aug;71(2):327-49.
5. Simpson EL, Bieber T, Guttman-Yassky E, et al. Two Phase 3 Trials of Dupilumab versus Placebo in Atopic Dermatitis. N Engl J Med. 2016 Dec 15;375(24):2335-2348.

6. Stevens WW, Schleimer RP, Kern RC. Chronic Rhinosinusitis with Nasal Polyps. J Allergy Clin Immunol Pract. 2016;4(4):565–572. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4939220/
7. Simpson EL, Paller AS, Siegfried EC, et al. Efficacy and Safety of Dupilumab in Adolescents With Uncontrolled Moderate to Severe Atopic Dermatitis: A Phase 3 Randomized Clinical Trial. JAMA Dermatol. 2020 Jan 1;156(1):44-56.
8. Dellon ES, Liacouras CA, Molina-Infante J, et.al. Updated International Consensus Diagnostic Criteria for Eosinophilic Esophagitis: Proceedings of the AGREE Conference.Gastroenterology. 2018;155(4):1022.
9. Hirano I, Chan ES, Rank MA, et.al. AGA institute and the joint task force on allergy-immunology practice parameters clinical guidelines for the management of eosinophilic esophagitis. Ann Allergy Asthma Immunol. 2020;124(5):416.
10. Hudgens S, Evans C, Phillips E, Hill M. Psychometric validation of the Dysphagia Symptom Questionnaire in patients with eosinophilic esophagitis treated with budesonide oral suspension. J Patient Rep Outcomes. 2017;1(1):3.

VII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/19/2017	New Policy creation
07/27/2017	Updated Exclusions section regarding physician samples
07/01/2018	Removed EHP Line of Business
11/28/2018	Added clinical criteria for Dupixent's asthma indication
04/24/2019	Clarified applicable age for the atopic dermatitis indication based on updated FDA-approved prescribing information
07/16/2019	Updated clinical criteria to account for new FDA-approved indication for CRSwNP
01/16/2020	Clarified exclusion criteria regarding concurrent biologic usage
07/15/2020	Updated criteria to account for lower FDA-approved age for atopic dermatitis; minor grammatical edits
10/20/2021	Updated criteria for AD with inclusion of objective evaluation tools, and Eucrisa trial for moderate disease
12/07/2021	Updated criteria based on FDA-approved prescribing information
07/20/2022	Added criteria to account for new FDA-approved indication for EoE
10/19/2022	Add criteria to account for new FDA-approved indication of PN; updated trial and failure criteria for AD
02/22/2023	Updated authorization guidance

10/18/2023	Updated clinical criteria

Revision Date: 04/19/2017, 07/27/2017, 07/01/2018, 11/28/2018, 04/24/2019, 07/16/2019, 01/16/2020, 07/15/2020, 10/20/2021, 12/07/2021, 07/20/2022, 10/19/2022, 02/22/2023, 10/18/2023

Review Date: 04/19/2017, 01/16/2019, 10/16/2019, 07/15/2020, 10/20/2021, 07/20/2022, 10/19/2022, 10/18/2023