Clinical Policy: Dupixent (dupilumab)

Reference Number: PHW.PDL.737.01
Effective Date: 01/01/2020
Last Review Date: 11/2024

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Dupixent (dupilumab) is **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Dupixent (dupilumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Dupixent (dupilumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Dupixent (dupilumab), the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**

5. If currently using a different Monoclonal Antibody (MAB)- Anti-IL, Anti-IgE, Anti-TSLP, will discontinue the other MAB- Anti-IL, Anti-IgE, Anti-TSLP prior to starting Dupixent (dupilumab); **AND**

6. If currently using a different targeted systemic Immunomodulator, Atopic Dermatitis (e.g., Adbry [tralokinumab], Cibinqo [abrocitinib], Rinvoq [upadacitinib]), will discontinue the other targeted systemic Immunomodulator, Atopic Dermatitis prior to starting Dupixent (dupilumab); **AND**

7. For a diagnosis of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:

    a. **One** of the following:
        i. For treatment of the face, skin folds, or other critical areas, a 4-week trial of a low-potency topical corticosteroid,
        ii. For treatment of areas other than the face or skin folds, or other critical areas, a 4-week trial of a medium- to high-potency topical corticosteroids,

    b. An 8-week trial of a topical calcineurin inhibitor,

    AND

8. For a diagnosis of asthma, **all** of the following:

    a. Has asthma severity consistent with the FDA-approved indication for Dupixent (dupilumab) despite maximal therapeutic doses of or intolerance or contraindication to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma,

    b. **One** of the following:

        i. Has absolute blood eosinophil count ≥ 150 cells/microL,
        ii. Is dependent on oral corticosteroids,

    c. Will use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

    AND

9. For a diagnosis of eosinophilic esophagitis, has a history of therapeutic failure of or a contraindication or an intolerance to a proton pump inhibitor; **AND**

10. For a diagnosis of prurigo nodularis, **both** of the following:

    a. Has a history of pruritis lasting at least 6 weeks

    b. Has prurigo nodularis associated with at least **one** of the following:

        i. ≥20 nodular lesions
        ii. Significant disability or impairment of physical, mental, or psychosocial functioning;

AND

11. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; **AND**

12. If a prescription Dupixent (dupilumab) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR DUPIXENT (DUPILUMAB):
The determination of medical necessity of a request for renewal of a prior authorization for Dupixent (dupilumab) that was previously approved will take into account whether the member:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**

3. Has documented evidence of improvement in disease severity; **AND**

4. For a diagnosis of asthma, **both** of the following:

   a. **One** of the following:

      i. Has documented measurable evidence of improvement in the severity of the asthma condition,
      ii. Has reduction of oral corticosteroid dose while maintaining asthma control,

   b. Continues to use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

AND

5. If a prescription Dupixent (dupilumab) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into

account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Dupixent (dupilumab). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the member.

D. **Approval Duration:**

New Request: 6 months
Renewal Request: 12 months

E. References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.: October 2022.
2. 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;375:2335-48.
3. Howe W, Paller AS, Butala S. Treatment of atopic dermatitis (eczema). In: UpToDate [internet database]. Dellavalle RP, Levy ML, Fowler J, Corona R, eds. Waltham, MA: UpToDate. Updated July 25, 2023. Accessed August 1, 2023.
4. Lio PA. Management of severe atopic dermatitis (eczema) in children. In: UpToDate [internet database]. Dellavalle RP, Levy ML, Fowler J, Corona R, eds. Waltham, MA: UpToDate. Updated June 28, 2022. Accessed August 1, 2023.
5. 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;71(2):327-49.
6. Boguniewicz M, Alexis AF, Beck LA, et al. Expert perspectives on management of moderate-to-severe atopic dermatitis: a multidisciplinary consensus addressing current and emerging therapies. J Allergy Clin Immunol Pract. 2017;5(6):1519-1531.
7. Wollenberg A, Christen-Zäch S, Taieb A, et al. ETFAD/EADV Eczema task force 2020 position paper on diagnosis and treatment of atopic dermatitis in adults and children. J Eur Acad Dermatol Venereol. 2020;34(12):2717-2744.
8. Drucker AM, Ellis AG, Bohdanowicz M, et al. Systemic immunomodulatory treatment for patients with atopic dermatitis – a systemic review and network meta-analysis. JAMA Dermatol. 2020;156(6):659-667.
9. Siegels D, Heratizadeh A, Abraham S, et al. Systemic treatments in the management of atopic dermatitis: a systematic review and meta-analysis. Allergy. 2021;76(4):1053-1076.

10. Sawangjit R, Dilokthornsakul P, Lloyd-Lavery A, Lai NM, Dellavalle R, Chaiyakunapruk N. Systemic treatments for eczema: a network meta-analysis. Cochrane Database Syst Rev. 2020;9:CD013206. Published 2020 Sep 14.
11. Atopic dermatitis yardstick: practical recommendations for an evolving therapeutic landscape. Ann Allergy Asthma Immunol. 2018;120:10-22.
12. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate [internet database]. Bochner BS, Hollingsworth H, eds. Waltham, MA: UpToDate. Updated March 23, 2022. Accessed April 18, 2022.
13. Global Initiative for Asthma. Global strategy for asthma management and prevention, 2022. http://www.ginasthma.org. Accessed April 18, 2022.
14. Global Initiative for Asthma. Difficult-to-treat & severe asthma in adolescents and adult patients – diagnosis and management, April 2019. http://www.ginasthma.org. Accessed May 3, 2021.
15. U.S. Department of Health, National Institutes of Health, National Heart, Lung, and Blood Institute. Expert panel report 3 (EPR-3): Guidelines for the diagnosis and management of asthma – Full Report 2007. https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthgdln_1.pdf. Published October 2007. Accessed April 18, 2022.
16. U.S. Department of Health, National Institutes of Health, National Heart, Lung, and Blood Institute. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Published December 2020.
17. Rosenfeld RM, Piccirillo JF, et al. Clinical practice guideline (update): adult sinusitis. Otolaryngol Head Neck Surg. 2015;152(2S):S1–S39.
18. Fokkens WJ, Lund V, Bachert C, et al. EUFOREA consensus on biologics for CRSwNP with or without asthma. Allergy. 2019;00:1–8.
19. Hamilos DL, Holbrook EH. Chronic rhinosinusitis: management. In: UpToDate [internet database]. Corren J, Deschler DG, Feldweg AM, eds. Waltham, MA: UpToDate. Updated February 17, 2021. Accessed May 5, 2021.
20. Sidbury R, Alikhan A, Bercovitch L, et al. Guidelines of care for the management of atopic dermatitis in adults with topical therapies. J Am Acad Dermatol. 2023;89(1):e1-e20.
21. Yosipovitch G, Mollanazar N, Ständer S, et al. Dupilumab in patients with prurigo nodularis: two randomized, double-blind, placebo-controlled phase 3 trials. Nat Med. 2023;29:1180-1190.
22. Ständer HF, Elmariah S, Zeidler C, Spellman M, Ständer S. Diagnostic and treatment algorithm for chronic prurigo nodularis. 2019. doi: 10.1016/j.jaad.2019.07.022.
23. Ständer S, Peraira MP, Berger T, et al. IFSI-guideline on chronic prurigo including prurigo nodularis. Itch. 2020;5(4):e42. doi: 10.1097/itx.0000000000000042.
24. Elmariah S, Kim B, Berger T, et al. Practical approaches for diagnosis and management of prurigo nodularis: United States expert panel consensus. J Am Acad Dermatol. 2021;84(3):747-760.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021
Q1 2023: policy revised according to DHS revisions effective 01/09/2023	10/2022
Q1 2024: policy revised according to DHS revisions effective 01/08/2024	11/2023
Q1 2025 annual review: no changes.	11/2024