Clinical Policy: Dupixent (dupilumab)

Reference Number: PHW.PDL.737.01
Effective Date: 01/01/2020
Last Review Date: 11/2025

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, Dermatologic (e.g., Adbry [tralokinumab], Cibinqo [abrocitinib], Nemluvio [nemolizumab], Rinvoq [upadacitinib]), will discontinue the other targeted systemic Immunomodulator, Dermatologic prior to starting Dupixent (dupilumab); **AND**

7. For a diagnosis of chronic atopic dermatitis, **both** of the following:

   a. Has atopic dermatitis associated with at least **one** of the following:
      i. A body surface area of 10% or greater that is affected,
      ii. Involvement of critical areas (e.g., face, feet, genitals, hands, intertriginous areas, scalp),
      iii. Significant disability or impairment of physical, mental, or psychosocial functioning
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to **both** of the following:
      i. **One** of the following:
         a) For treatment of the face, skin folds, or other critical areas, a 4-week trial of a low-potency topical corticosteroid,
         b) For treatment of other areas, a four-week trial of a medium-potency or higher topical corticosteroid,
      ii. 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 a contraindication or an intolerance to asthma controller drugs based on current national treatment guidelines for the diagnosis and management of asthma,

   b. **One** of the following:

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

   c. Will use Dupixent (dupilumab) in addition to standard asthma controller drugs 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 a diagnosis of bullous pemphigoid, **both** of the following:

    a. One of the following:

        i. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic corticosteroids
        ii. Has corticosteroid-dependent disease

    b. One of the following:

        i. Has a history of therapeutic failure of a corticosteroid-sparing therapy (e.g., doxycycline, dapsone, methotrexate, mycophenolate, azathioprine)
        ii. Has a contraindication or an intolerance to corticosteroid-sparing therapies;

12. 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**

13. 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 drugs 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

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13. 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.
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15. 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.
16. 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.
17. 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.
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Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020

Reviews, Revisions, and Approvals	Date
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
Q1 2026: policy revised according to DHS revisions effective 01/05/2026.	11/2025