Clinical Policy: Dupixent (dupilumab)

Reference Number: PHW.PDL.737.01
Effective Date: 01/01/2020
Last Review Date: 10/2022

Revision Log

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. For treatment of moderate-to-severe chronic atopic dermatitis, has a history of therapeutic failure, of at least **two** of the following or a contraindication, or intolerance to **all** 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,

c. Phototherapy in accordance with current consensus guidelines,

d. Systemic immunosuppressives in accordance with current consensus guidelines (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil);

AND

7. 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

8. 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**

9. 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**

10. 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.

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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16. 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.
17. 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.
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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