PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
DUPIXENT (DUPILUMAB)

Proposed Effective Date: July 8, 2019

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

I. Requirements for Prior Authorization of Dupixent (dupilumab)

A. Prescriptions That Require Prior Authorization

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

The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Revisions to Clinical Review Guidelines and 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 beneficiary:

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

3. Is prescribed Dupixent (dupilumab) by or in consultation with a**n appropriate** specialist (i.e. dermatologist, immunologist, allergist, pulmonologist, etc.); **AND**

4. Will be evaluated, treated, and/or monitored for parasitic (helminth) infection before and/or during treatment with Dupixent (dupilumab) as recommended in FDA-approved package labeling; **AND**

5. For treatment of chronic moderate to severe atopic dermatitis, **all** of the following:

    a. Has a documented history of therapeutic failure, contraindication, or intolerance to **one** of the following topical pharmacologic treatments:

        i. For treatment of the face or skin folds, low-potency topical corticosteroids,
        ii. For treatment of areas other than the face or skin folds, medium- to high-potency topical corticosteroids,
        iii. Topical calcineurin inhibitors,

    b. Has a documented history of therapeutic failure, contraindication, or intolerance to phototherapy in accordance with current consensus guidelines,

    c. Has a history of therapeutic failure, contraindication, or intolerance to systemic

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

AND

6. 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. If an eosinophilic phenotype, has absolute blood eosinophil count ≥ 150 cells/microL,

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

   AND

7. **One of the following:**

   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred agents approved for the indication
   b. **Has a current history (within the past 90 days) of being prescribed Dupixent (dupilumab);**

   AND

8. 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 the Quantity Limits Chapter.

   NOTE: If the beneficiary 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 beneficiary, 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 beneficiary:

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 (i.e. dermatologist, immunologist, allergist, pulmonologist, etc.); **AND**

3. Is being monitored and treated, if applicable, for parasitic (helminth) infection as recommended in the FDA-approved package labeling; **AND**

4. For a diagnosis of atopic dermatitis, has documented evidence of improvement in disease severity; **AND**

5. 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

6. 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 the Quantity Limits Chapter.

   NOTE: If the beneficiary 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 beneficiary, 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 beneficiary.

D. References

1. Dupixent [package insert]. Tarrytown, NY: Regeneron Pharmaceuticals, Inc.: October 2018.

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7. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate [internet database]. Bochner BS, Hollingsworth, H, eds. Waltham, MA: UpToDate. Updated December 4, 2018. Accessed February 7, 2019.
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9. 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 February 7, 2019.