pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 4, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Dupixent (dupilumab) – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Dupixent (dupilumab) submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service delivery system. Providers rendering services in the MA managed care delivery system should address any questions related to Dupixent (dupilumab) to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists

*01-19-102	09-19-98	27-19-97	33-19-99
02-19-96	11-19-95	30-19-94	
03-19-95	14-19-94	31-19-102	
08-19-105	24-19-97	32-19-94	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type

Visit the Office of Medical Assistance Programs Web site at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

through the Department's Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the September 13, 2019, meeting, the DUR Board recommended the addition of guidelines to address the recent U.S. Food and Drug Administration approval of Dupixent (dupilumab) as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis and the addition of a guideline that Dupixent will not be used in combination with another Monoclonal Antibody – Anti-IL, Anti-IgE.

The revisions to the guidelines to determine medical necessity of Dupixent (dupilumab), as recommended by the DUR Board, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of Dupixent (dupilumab) are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Dupixent (dupilumab) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

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 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 an appropriate specialist (e.g., dermatologist, immunologist, allergist, pulmonologist, otolaryngologist, 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. Will not use Dupixent (dupilumab) in combination with another Monoclonal Antibody – Anti-IL, Anti-IgE; **AND**

6. 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

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. 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

8. For a diagnosis of chronic rhinosinusitis with nasal polyposis (CRSwNP), has a documented history of therapeutic failure, contraindication, or intolerance to **all** of the following:

   a. At least a 14-day course of systemic glucocorticoids,
   b. Sino-nasal surgery,
   c. Maintenance nebulized or irrigated intranasal glucocorticoids;

   AND

9. **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

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 the Quantity Limits Chapter. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

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

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

4. Will not use Dupixent (dupilumab) in combination with another Monoclonal Antibody – Anti-IL, Anti-IgE; **AND**

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

6. 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

7. 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. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   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

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