


ISSUE DATE November 5, 2021	EFFECTIVE DATE January 3, 2022	NUMBER *See below
SUBJECT Prior Authorization of Dupixent (dupilumab) – Pharmacy Services		BY  Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs

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. The guidelines to determine the medical necessity of Dupixent (dupilumab) will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of Dupixent (dupilumab) to the appropriate MCO.

BACKGROUND:

*01-21-29	09-21-28	27-21-20	33-21-28
02-21-16	11-21-18	30-21-23	
03-21-16	14-21-19	31-21-31	
08-21-31	24-21-26	32-21-16	

<p>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</p> <p>The appropriate toll-free number for your provider type.</p> <p>Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.</p>

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 15, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of Dupixent (dupilumab):

- Removal of the guideline that for all diagnoses Dupixent (dupilumab) is prescribed by or in consultation with an appropriate specialist;
- Removal of the guideline related to parasitic (helminth) infection;
- Revision of the guideline related to the concomitant use of Dupixent with another Monoclonal Antibody, Anti-IL, Anti-IgE;
- Revision of the guidelines for the treatment of atopic dermatitis based on consultation with a board-certified dermatologist;
- Revision of the guidelines for the treatment of asthma; and
- Removal of the guidelines for chronic rhinosinusitis with nasal polyposis.

The revisions to the guidelines to determine medical necessity of prescriptions for Dupixent (dupilumab) submitted for prior authorization, as recommended by the P&T Committee, 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx>

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines

<https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx>

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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. If currently using a different Monoclonal Antibody (MAB) – Anti-IL, Anti-IgE, will discontinue the other MAB – Anti-IL, Anti-IgE prior to starting Dupixent (dupilumab); **AND**
4. 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 an intolerance to **all** of the following:
 - a. **One** of the following:
 - i. For treatment of the face, skin folds, or other critical areas, a low-potency topical corticosteroid
 - ii. For treatment of other areas, a medium-potency or higher topical corticosteroid,
 - b. 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

2. For a diagnosis of asthma, **all** of the following:
 - a. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., allergist, immunologist, pulmonologist),

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- b. 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,
- c. **One** of the following:
 - i. Has absolute blood eosinophil count ≥ 150 cells/microL
 - ii. Is dependent on oral corticosteroids,
- d. Will use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

AND

- 3. 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. For a diagnosis of atopic dermatitis or chronic rhinosinusitis with nasal polyposis, has documented evidence of improvement in disease severity; **AND**
- 3. For a diagnosis of asthma, **all** of the following:
 - a. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., allergist, immunologist, pulmonologist),
 - b. **One** of the following:
 - i. Has documented measurable evidence of improvement in the severity of the

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- asthma condition
- ii. Has reduction of oral corticosteroid dose while maintaining asthma control,
 - c. Continues to use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

AND

4. 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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