pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

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August 8, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Monoclonal Antibodies - Anti-IL, Anti-IgE (MABs – Anti-IL, Anti-IgE) – 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: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

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 MABs – Anti-IL, Anti-IgE 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 MABs – Anti-IL, Anti-IgE to the appropriate managed care organization.

BACKGROUND:

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

*01-19-24	09-19-22	27-19-20	33-19-22
02-19-19	11-19-18	30-19-18	
03-19-18	14-19-18	31-19-24	
08-19-27	24-19-20	32-19-18	

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
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

- 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 May 15, 2019, meeting, the P&T Committee recommended that the Department add Dupixent (dupilumab) to the MABs – Anti-IL, Anti-IgE class of drugs on the PDL due to its similar mechanism of action with other agents in this class and the recent U.S. Food and Drug Administration approval for the treatment of asthma with eosinophilic phenotype or oral corticosteroid-dependent asthma.

The Department's Drug Utilization Review (DUR) Board recommended guidelines to determine medical necessity of Dupixent (dupilumab) that address the new asthma indication at the March 21, 2019, meeting. Recognizing that Dupixent (dupilumab) is now indicated for both asthma and atopic dermatitis, the Department published guidelines specific to Dupixent (dupilumab) that address both indications.

The Department is updating the MABs – Anti-IL, Anti-IgE guidelines to include a reference to the medical necessity guidelines for Dupixent (dupilumab). There are no other changes to the medical necessity guidelines for MABs – Anti-IL, Anti-IgE.

The revisions to the guidelines to determine medical necessity of MABs – Anti-IL, Anti-IgE 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 MABs – Anti-IL, Anti-IgE 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 MABs – Anti-IL, Anti-IgE) 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
http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm

I. Requirements for Prior Authorization of Monoclonal Antibodies - Anti-IL, Anti-IgE (MABs – Anti-IL, Anti-IgE)

A. Prescriptions That Require Prior Authorization

All prescriptions for MABs – Anti-IL, Anti-IgE must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a MAB – Anti-IL, Anti-IgE, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Dupixent (dupilumab), see the provider handbook pages in the SECTION II chapter related to Dupixent (dupilumab); **OR**

2. Is prescribed the MAB – Anti-IL, Anti-IgE for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

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

5. Is prescribed the MAB – Anti-IL, Anti-IgE by or in consultation with an appropriate specialist (ie, pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.); **AND**

6. Received appropriate vaccinations as recommended in the FDA-approved package labeling unless contraindicated; **AND**

7. Will be evaluated, treated, and/or monitored for parasitic (helminth) infection before and/or during treatment with the prescribed MAB - Anti-IL, Anti-IgE as recommended in FDA-approved package labeling; **AND**

8. For a non-preferred MAB - Anti-IL, Anti-IgE, **one** of the following:

    a. Has a documented history of therapeutic failure, intolerance, or contraindication of the preferred MAB - Anti-IL, Anti-IgE approved or medically accepted for the beneficiary's indication
    b. Has a current history (within the past 90 days) of being prescribed the same non-preferred MAB - Anti-IL, Anti-IgE

See the Preferred Drug List (PDL) for the list of preferred MABs – Anti-IL, Anti-IgE at: https://papdl.com/preferred-drug-list;

AND

9. For a diagnosis of asthma, **both** of the following:

   a. Has an asthma severity that is consistent with the FDA-approved indication for the prescribed MAB - Anti-IL, Anti-IgE 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. Will use the requested MAB - Anti-IL, Anti-IgE in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma;

AND

10. For a diagnosis of chronic idiopathic urticaria, **both** of the following:

    a. Has a documented history of urticaria for a period of at least 3 months

    b. **One** of the following:

       i. Requires steroids to control urticarial symptoms

       ii. Has a documented history of therapeutic failure, contraindication, or intolerance to maximum tolerated doses of **all** of the following:

          a) H1 antihistamine,
          b) H2 antihistamine,
          c) Leukotriene modifier,
          d) Dapsone, sulfasalazine, or hydroxychloroquine;

AND

11. For a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), **both** of the following:

    a. Has a diagnosis of EGPA supported by **all** of the following:

       i. A documented history of asthma,

       ii. A documented history of absolute blood eosinophil count ≥ 1000 cells/microL or blood eosinophil level > 10% of leukocytes,

       iii. A documented history of at least **one** of the following:

a) Histopathological evidence of **one** of the following:

1) Eosinophilic vasculitis,
2) Perivascular eosinophilic infiltration,
3) Eosinophil-rich granulomatous inflammation,

b) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality),
c) Pulmonary infiltrates, non-fixed,
d) Sino-nasal abnormality,
e) Cardiomyopathy,
f) Glomerulonephritis,
g) Alveolar hemorrhage,
h) Palpable purpura,
i) Positive test for ANCA,

b. Has a documented history of therapeutic failure of ≥ 3 months of prednisolone ≥ 7.5 mg/day (or equivalent) unless intolerant or contraindicated;

AND

12. For Xolair (omalizumab) for a diagnosis of asthma, **both** of the following:

a. Has a diagnosis of allergen-induced asthma (allergic asthma confirmed by either a positive skin test or radioallergosorbent test [RAST]) to an unavoidable perennial aeroallergen (eg. pollen, mold, dust mite, etc.)
b. Has a serum total IgE measurement is between 30 International Units/mL and 1300 International Units/mL;

AND

13. For Cinqair (reslizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 400 cells/microL; **AND**

14. For Nucala (mepolizumab) for a diagnosis of asthma, has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**

15. For Fasenra (benralizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**

16. If a prescription for a MAB - Anti-IL, Anti-IgE is for 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. 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.

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 MABS - ANTI-IL, ANTI-IGE: The determination of medical necessity of a request for renewal of a prior authorization for a MAB - Anti-IL, Anti-IgE 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 a MAB - Anti-IL, Anti-IgE by or in consultation with an appropriate specialist (ie, pulmonologist, allergist, immunologist, dermatologist, rheumatologist, 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 asthma, **both** of the following:

   a. Has documented measurable evidence of improvement in the severity of the asthma condition
   b. Continues to use the requested MAB - Anti-IL, Anti-IgE in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma;

   AND

5. For a diagnosis of chronic idiopathic urticaria, has documentation of **both** of the following:

   a. Improvement of symptoms
   b. Rationale for continued use;

   AND

6. For a diagnosis of EGPA, has documented measurable evidence of improvement in disease activity; **AND**

7. If a prescription for a MAB - Anti-IL, Anti-IgE is for 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. 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.

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 a MAB - Anti-IL, Anti-IgE. 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. Dose and Duration of Therapy

Requests for prior authorization of a MAB - Anti-IL, Anti-IgE will be approved as follows:

1. For a diagnosis of EGPA:
   a. Initial requests for prior authorization of a MAB - Anti-IL, Anti-IgE will be approved for up to 6 months.
   b. Renewals of requests for prior authorization of a MAB - Anti-IL, Anti-IgE will be approved for up to 12 months.

2. For a diagnosis of chronic idiopathic urticaria:
   a. Initial and renewal requests for prior authorization of a MAB - Anti-IL, Anti-IgE will be approved for up to 6 months.

E. References

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18. Supplementary appendix to: Wechsler, ME et.al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. The New England Journal of Medicine. 2017;376:1921-32.