pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
July 23, 2018	July 23, 2018	*See below

SUBJECT

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

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers of the addition of the MABs-Anti-IL, Anti-IgE class of drugs to the Preferred Drug List (PDL); and
2. Issue 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 under the MA managed care delivery system should address any questions related to MABs-Anti-IL, Anti-IgE to the appropriate managed care organization.

*01-18-15	09-18-16	27-18-14	33-18-15
02-18-10	11-18-10	30-18-10	
03-18-10	14-18-11	31-18-16	
08-18-17	24-18-11	32-18-10	

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

BACKGROUND:

The Department of Human Services' (DHS) Pharmacy and Therapeutics (P&T) Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the following:

- New drugs in therapeutic classes already included in the 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 the PDL; and
- Guidelines to determine medical necessity.

DISCUSSION:

During the May 16, 2018, meeting, the P&T Committee recommended the addition of the MABs-Anti-IL, Anti-IgE class of drugs to the PDL. Several drugs within this class, Cinqair (reslizumab), Nucala (mepolizumab), and Xolair (omalizumab), already require a clinical prior authorization for health and safety reasons based upon recommendations of the DHS Drug Utilization Review (DUR) Board. The handbook pages describing the requirements for prior authorization of MABs-Anti-IL, Anti-IgE, the guidelines to determine medical necessity and the dose and duration of therapy represent a merger of the current handbook pages for Cinqair (reslizumab), Nucala (mepolizumab), and Xolair (omalizumab). They also recognize recent U.S. Food and Drug Administration actions regarding Fasenra, Nucala and Xolair. The requirements for prior authorization and the medical necessity guidelines were subject to public review and comment, and subsequently approved for implementation by DHS.

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. DHS 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

SECTION II
MABs-Anti-IL, Anti-IgE

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

A. Prescriptions That Require Prior Authorization

Prescriptions for MABs - Anti-IL, Anti-IgE that meet any of the following conditions must be prior authorized:

1. A preferred or non-preferred MAB - Anti-IL, Anti-IgE. See the Preferred Drug List (PDL) for the list of preferred MABs, Anti-IL, Anti-IgE: https://papdl.com/preferred-drug-list

2. A prescription for MABs - Anti-IL, Anti-IgE with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

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

1. The beneficiary is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package insert OR a medically-accepted indication

AND

2. The beneficiary is age-appropriate according to FDA-approved package labeling or nationally recognized compendia

AND

3. The requested dose is consistent with FDA-approved package labeling or nationally recognized compendia for the beneficiary's diagnosis, age, and concomitant medical conditions

AND

4. The MAB - Anti-IL, Anti-IgE is prescribed by, or in consultation with, an appropriate specialist (ie, pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.)

AND

5. The beneficiary received appropriate vaccinations as recommended in the FDA-approved package labeling unless contraindicated

AND

6. The beneficiary 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

7. For a non-preferred MAB - Anti-IL, Anti-IgE, the beneficiary has a documented history of therapeutic failure or intolerance of or contraindication to the preferred MAB - Anti-IL, Anti-IgE approved for the beneficiary's indication

OR

8. The beneficiary has a current history (within the past 90 days) of being prescribed the same non-preferred MAB - Anti-IL, Anti-IgE

AND

9. For a diagnosis of asthma:

   a. The beneficiary's asthma severity is consistent with the FDA-approved indication for the prescribed MAB - Anti-IL, Anti-IgE, despite maximal therapeutic doses of, intolerance, or contraindication to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma

   AND

   b. The beneficiary will use the requested MAB - Anti-IL, Anti-IgE in addition to standard asthma controller medications as recommended by current national treatment guidelines

AND

10. For a diagnosis of chronic idiopathic urticaria, the beneficiary:

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

AND

b. Requires steroids to control urticarial symptoms

OR

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

i. H_1 antihistamine
ii. H_2 antihistamine
iii. Leukotriene modifier
iv. Dapsone, sulfasalazine, or hydroxychloroquine

AND

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

a. Has a diagnosis of EGPA supported by:

i. A documented history of asthma

AND

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

AND

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

AND

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, the beneficiary:

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.)

AND

b. Has a serum total IgE measurement is between 30 International Units/mL and 1300 International Units/mL.

AND

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

AND

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

AND

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

16. In addition, iIf a prescription for either a preferred or non-preferred MAB - Anti-IL, Anti-IgE 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: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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 PRESCRIPTIONS FOR MABs - Anti-IL, Anti-IgE: The determination of medical necessity of renewals of prescriptions for MABs - Anti-IL, Anti-IgE that were previously submitted for prior authorization and approved will take into account whether the beneficiary:

1. Is prescribed a dose consistent with FDA-approved package labeling for the beneficiary's diagnosis, age, and concomitant medical conditions

AND

2. Is prescribed the 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:

   a. Has documented measurable evidence of improvement in the severity of the asthma condition

   AND

   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

AND

5. For a diagnosis of chronic idiopathic urticaria, has documentation of:

a. Improvement of symptoms

AND

b. Rationale for continued use

AND

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

7. In addition, iIf a prescription for either a preferred or non-preferred MAB - Anti-IL, Anti-IgE 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: As described in Section C, if the beneficiary does not meet the clinical review guidelines and/or the quantity limit 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 the request. 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 an MAB - Anti-IL, Anti-IgE will be approved as follows:

1. For a diagnosis of asthma and EGPA:

a. The initial prescription will be approved for a period of up to six (6) months.

b. Renewals of prescriptions that were previously approved will be approved for a period of up to 12 months.

2. For a diagnosis of chronic idiopathic urticaria, both initial prescriptions and renewals of prescriptions that were previously approved will be approved for a period of up to 6 months.

E. References:

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7. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate. Updated December 19, 2016. Accessed January 30, 2017.
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13. Fasenra (benralizumab) [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; November 2017.
14. Lantham JG et.al. Systemic vasculitis with asthma and eosinophilia: a clinical approach to the Churg-Strauss syndrome. Medicine.1984 Mar;63(2):65-81.
15. Masi AT, etal. The American College of Rheumatology 1990 criteria for the classification of Churg-Strauss syndrome (allergic granulomatosis and angiitis). Arthritis and Rheumatism. 1990 Aug;33(8):1094-100.
16. King TE. Clinical features and diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). UpToDate. Updated September 12, 2017. Accessed January 26, 2018.
17. Wechsler ME, Akuthota P, Jayne D, et.al. Mepolizumab or Placebo for Eosinophilic Granulomatosis with Polyangiitis. The New England Journal of Medicine. 2017;376:1921-32.
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.