pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
December 5, 2019	January 1, 2020	*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: 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 Monoclonal Antibodies – Anti-IL, Anti-IgE (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/DISCUSSION:

The Department of Human Services (Department) is updating the medical necessity guidelines for MABs – Anti-IL, Anti-IgE to add a guideline that the requested MAB – Anti-IL,

*01-19-107	09-19-103	27-19-102	33-19-104
02-19-101	11-19-100	30-19-99	
03-19-100	14-19-99	31-19-107	
08-19-110	24-19-102	32-19-99	

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.

Anti-IgE will not be used in combination with another MAB – Anti-IL, Anti-IgE. There are no other changes to the medical necessity guidelines.

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

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 (i.e., 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. Will not use the requested MAB – Anti-IL, Anti-IgE in combination with another MAB – Anti-IL, Anti-IgE; **AND**

9. 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 for the list of preferred MABs – Anti-IL, Anti-IgE at: https://papdl.com/preferred-drug-list;

AND

10. 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

11. 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

12. 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

13. 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) to an unavoidable perennial aeroallergen (e.g., pollen, mold, dust mite, etc.)
b. Has a serum total IgE measurement is between 30 International Units/mL and 1300 International Units/mL;

AND

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

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

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

17. 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: 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 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 (i.e., 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. Will not use the requested MAB – Anti-IL, Anti-IgE in combination with another MAB – Anti-IL, Anti-IgE; **AND**

5. 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

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

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

   AND

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

8. 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: 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 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

1. Cinqair (reslizumab) [package insert]. Frazer, PA: Teva Respiratory, LLC.; Revised March 2016.
2. Castro M, Zangrilli J, Wechsler ME, et al. Reslizumab for inadequately controlled asthma with elevated blood eosinophil counts: results from two multicentre, parallel, double-

blind, randomised, placebo-controlled, phase 3 trials. Lancet Respir Med. 2015;3(5):355-66. doi: 10.1016/S2213-2600(15)00042-9.
3. Bjermer L, Lemiere C, Maspero J, Weiss S, Zangrilli J, Germinaro M. Reslizumab for inadequately controlled asthma with elevated blood eosinophil levels: a randomized phase 3 study. Chest. 2016;150(4):789-98.
4. Corren J, Weinstein S, Janka L, Zangrilli J, Garin M. Phase 3 study of reslizumab in patients with poorly controlled asthma: effects across a broad range of eosinophil counts. Chest. 2016;150(4):799-810.
5. Nucala (mepolizumab) [package insert]. Research Triangle Park, NC: GlaxoSmithKline. Revised December 2017.
6. Xolair (omalizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; Revised June 2017.
7. Wenzel S. Treatment of severe asthma in adolescents and adults. In: UpToDate. Updated December 19, 2016. Accessed January 30, 2017.
8. Weller P, Klion AD. Eosinophil biology and causes of eosinophilia. In: Up To Date. Updated December 5, 2017. Accessed February 5, 2018.
9. Khan DA. Chronic urticaria: treatment of refractory symptoms. In: UpToDate [internet database]. Saini S, Callen J, Feldweg AM, eds. Waltham, MA: UpToDate. Updated July 7, 2016. Accessed January 31, 2017.
10. Legrand F, Klion AD. Biologic therapies targeting eosinophils: current status and future prospects. J Allergy Clin Immunol Pract. 2015;3:167-74. doi: 10.1016/j.jaip.2015.01.013.
11. Global Initiative for Asthma. Global Strategy for Asthma Management and Prevention, 2017. http://www.ginasthma.org. Accessed February 5, 2018.
12. 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 5, 2018.
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.