PA DEPARTMENT OF HUMAN SERVICES
MAAC BRIEFING DOCUMENT
MONOCLONAL ANTIBODIES – ANTI-IL, ANTI-IgE

Proposed Effective Date: July 8, 2019

Revisions are noted with a ~~strikethrough~~ for deletions and **bold and underline** for additions.

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

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for MABs – Anti-IL, Anti-IgE 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 **at**: 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~~ 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.

B. Revisions to 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. ~~The beneficiary~~ 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**

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

4. ~~The requested~~ **Is prescribed a** dose that is consistent with FDA-approved package labeling**,** ~~or~~ nationally recognized compendia**, or peer-reviewed medical literature** ~~for the beneficiary's diagnosis, age, and concomitant medical conditions;~~ **AND**

5. ~~The MAB – Anti-IL, Anti-IgE~~ 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. ~~The beneficiary~~ Received appropriate vaccinations as recommended in the FDA-approved package labeling unless contraindicated; **AND**

7. ~~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**

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

   a. ~~the beneficiary~~ Has a documented history of therapeutic failure, intolerance ~~of~~, or contraindication **of** ~~to~~ the preferred MAB - Anti-IL, Anti-IgE approved **or medically-accepted** for the beneficiary's indication

   b. ~~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**, both of the following**:

   a. ~~The beneficiary's~~ **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. ~~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 **for the diagnosis and management of asthma**;

   AND

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

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

    b. **One of the following:**

       i. Requires steroids to control urticarial symptoms

       ii. Has a documented history of therapeutic failure**,** ~~or~~ contraindication**,** ~~of~~ 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), ~~the beneficiary~~ **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, ~~the beneficiary~~ **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), ~~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**; AND**

16. ~~In addition,~~ 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.

    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 PRIOR AUTHORIZATION FOR MABs - Anti-IL, Anti-IgE: The determination of medical necessity of **a request for** renewal~~s~~ of ~~prescriptions~~ **a prior authorization** for **a** MAB~~s~~ - Anti-IL, Anti-IgE that **was** ~~were~~ 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** ~~for the beneficiary's diagnosis, age, and concomitant medical conditions~~; **AND**

2. Is prescribed ~~the~~ **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. ~~In addition,~~ If a prescription for ~~either a preferred or non-preferred~~ **a** MAB - Anti-IL, Anti-IgE is ~~in~~ **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.

   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~~ **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. ~~The~~ Initial ~~prescription~~ **requests for prior authorization of a MAB - Anti-IL, Anti-IgE** will be approved for ~~a period~~ up to six (6) months.
   b. Renewals of ~~prescriptions that were previously approved~~ **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 ~~prescriptions~~ and renewal~~s of prescriptions that were previously approved~~ **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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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.