Clinical Policy: Monoclonal Antibodies - Anti-IL, Anti-IgE, Anti-TSLP

Reference Number: PHW.PDL.737
Effective Date: 01/01/2020
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Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Monoclonal Antibodies - Anti-IL, Anti-IgE, Anti-TSLP are **medically necessary** when the following criteria are met:

I. Requirements for Prior Authorization of Monoclonal Antibodies - Anti-IL, Anti-IgE, Anti-TSLP

A. Prescriptions That Require Prior Authorization

All prescriptions for MABs – Anti-IL, Anti-IgE, Anti-TSLP 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, Anti-TSLP, the determination of whether the requested prescription is medically necessary will take into account whether the member:

1. For Dupixent (dupilumab), see PHW.PDL.737.01 Dupixent (dupilumab); **OR**

2. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP 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, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**

6. If currently using a different MAB – Anti-IL, Anti-IgE, Anti-TSLP than requested, will discontinue the other MAB – Anti-IL, Anti-IgE, Anti-TSLP prior to starting the requested agent; **AND**

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

   a. Has a history of therapeutic failure, intolerance, or contraindication of the preferred MAB - Anti-IL, Anti-IgE, Anti-TSLP approved or medically accepted for the member's indication,
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred MAB - Anti-IL, Anti-IgE, Anti-TSLP (does not apply to non-preferred brands when the therapeutically equivalent interchangeable biosimilar or unbranded biologic is preferred or to non-preferred interchangeable biosimilars or unbranded biologics when the therapeutically equivalent interchangeable brand or brand biologic is preferred).

   AND

8. 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, Anti-TSLP 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, Anti-TSLP in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma;

   AND

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

   a. Has a history of urticaria for a period of at least 6 weeks,

   b. **One** of the following:

      i. Requires systemic steroids to control urticarial symptoms,

      ii. Has a history of therapeutic failure, contraindication, or intolerance to maximum tolerated doses of an H1 antihistamine taken for at least 2 weeks,

   AND

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

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

i. A history of asthma,

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

iii. A 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. One of the following:
i. Requires systemic glucocorticoids to maintain remission,
ii. Has a contraindication or an intolerance to systemic glucocorticoids,
c. For a beneficiary with severe EGPA as defined by national treatment guidelines, has a history of therapeutic failure of or a contraindication or an intolerance to rituximab or cyclophosphamide;

AND

11. For a diagnosis of hypereosinophilic syndrome (HES), **all** of the following:

a. Has documented FIP1L1-PDGFRA–negative HES with organ damage or dysfunction,

b. Has a documented blood eosinophil count ≥ 1000 cells/microL,

c. **One** of the following:

i. Requires or has required systemic glucocorticoids to maintain remission,
ii. Has contraindication or intolerance of systemic glucocorticoids,

AND

12. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; AND

13. For Xolair (omalizumab) for a diagnosis of asthma, 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.); **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, Anti-TSLP 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 PA.CP.PMN.59 Quantity Limit Override.

    NOTE: If the member 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 member, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MABS - ANTI-IL, ANTI-IGE, Anti-TSLP: The determination of medical necessity of a request for renewal of a prior authorization for a MAB - Anti-IL, Anti-IgE, Anti-TSLP that was previously approved will take into account whether the member:

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, Anti-TSLP by or in consultation with an appropriate specialist (ie, pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.); **AND**

3. Is not using the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in combination with another MAB – Anti-IL, Anti-IgE, Anti-TSLP; **AND**

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

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

b. Continues to use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP 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, **both** of the following:

   a. Experienced improvement of symptoms,
   b. Has a documented rationale for continued use;

   AND

6. For a diagnosis of HES or EGPA, has **one** of the following:

   a. Measurable evidence of improvement in disease activity,
   b. Reduction in use of systemic glucocorticoids for this indication;

   AND

7. For a non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP with a therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that is preferred on the PDL, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred therapeutically equivalent interchangeable biosimilar or brand or unbranded biologic that would not be expected to occur with the requested medication.

8. If a prescription for a MAB - Anti-IL, Anti-IgE, Anti-TSLP 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 PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the member 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 member, 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, Anti-TSLP. 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 member.

D. **Dose and Duration of Therapy**

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

Initial: 6 months
Reauthorization: 12 months

E. References

1. Cinqair (reslizumab) [package insert]. Frazer, PA: Teva Respiratory, LLC.; Revised January 2019.
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https://www.nhlbi.nih.gov/sites/default/files/media/docs/asthgdln_1.pdf. Published October, 2007. Accessed February 5, 2018.
14. U.S. Department of Health, National Institutes of Health, National Heart, Lung, and Blood Institute. 2020 Focused Updates to the Asthma Management Guidelines: A Report from the National Asthma Education and Prevention Program Coordinating Committee Expert Panel Working Group. Published December 2020.
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17. Chung SA, Langford CA, Maz M, et al. 2021 American College of Rheumatology/Vasculitis Foundation Guideline for the Management of Antineutrophil Cytoplasmic Antibody-Associated Vasculitis. Arthritis Care & Research. 2021;73(8):1088-1105. doi:10.1002/acr.24634.
18. King TE. Clinical features and diagnosis of eosinophilic granulomatosis with polyangiitis (Churg-Strauss). UpToDate. Updated March 22, 2022. Accessed June 30, 2022.
19. King TE. Eosinophilic granulomatosis with polyangiitis (Churg-Strauss): Treatment and prognosis. UpToDate. Updated May 10, 2022. Accessed June 30, 2022.
20. 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.
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Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022: revised according to DHS revisions effective 01/03/2022	10/2021
Q1 2023: revised according to DHS revisions effective 01/09/2023	10/2022
Q1 2024 annual review: no changes.	11/2023