

**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 CP-206.168-MD-PA Dupixent (dupilumab) Policy; **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  $\geq 1000$  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  $\geq 3$  months of prednisolone  $\geq 7.5$  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  $\geq 400$  cells/microL; **AND**
14. For Nucala (mepolizumab) for a diagnosis of asthma, has asthma with an eosinophilic phenotype with absolute blood eosinophil count  $\geq 150$  cells/microL; **AND**
15. For Fasentra (benralizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count  $\geq 150$  cells/microL

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

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.

**MONOCLONAL ANTIBODIES (MABs) – ANTI-IL, ANTI-IgE PRIOR AUTHORIZATION FORM** (Form effective 1/1/20)

<input type="checkbox"/> New request <input type="checkbox"/> Renewal request		Total # of pages: _____	Prescriber name:	
Name of office contact:		Specialty:		
Contact's phone number:		NPI:	State license #:	
LTC facility contact/phone:		Street address:		
Beneficiary name:		Suite #:	City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:	
Medication will be billed via: <input type="checkbox"/> Pharmacy <input type="checkbox"/> Medical (Jcode: _____)		Place of Service: <input type="checkbox"/> Hospital <input type="checkbox"/> Provider's Office <input type="checkbox"/> Home <input type="checkbox"/> Other		

**CLINICAL INFORMATION**

Drug requested:	Strength:	Dosage form (pen, vial, etc):
Dose & directions:	Quantity:	Duration: _____ months
Diagnosis:	Dx code ( <i>required</i> ):	Weight: _____ lbs / kg
Has the beneficiary used the requested medication in the past 90 days? <i>Submit documentation.</i>		<input type="checkbox"/> Yes <input type="checkbox"/> No
Will the beneficiary be evaluated, monitored, and treated (if applicable) for helminth infection?		<input type="checkbox"/> Yes <input type="checkbox"/> No

**INITIAL requests**

<b>For a non-preferred drug in this class:</b> Does the beneficiary have a history of trial and failure of or contraindication or intolerance to the preferred agents in this class that are approved or medically accepted for treatment of the beneficiary's condition? Refer to <a href="https://papdl.com/preferred-drug-list">https://papdl.com/preferred-drug-list</a> for a list of preferred and non-preferred agents in this class.	<input type="checkbox"/> Yes <i>Submit documentation.</i> <input type="checkbox"/> No
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Complete all sections applicable to the beneficiary and this request. Check all that apply and **SUBMIT DOCUMENTATION** for each item.

- For treatment of asthma:**
- Is currently receiving optimally titrated doses of, or has a contraindication or intolerance to, the following (*check all that apply*):
    - inhaled glucocorticoid                       long-acting beta-agonist (LABA)
    - leukotriene modifier                               other (eg, tiotropium, theophylline): \_\_\_\_\_
  - For an anti-IgE MAB (eg Xolair):**
    - Has moderate-to-severe persistent asthma induced by an unavoidable perennial allergen (pollen, mold, dust mites, etc)
    - Diagnosis confirmed by positive skin test or radioallergosorbent test (RAST)
    - Has a serum total IgE measurement between 30 international units (IU)/mL and 1300 IU/mL
  - For an anti-IL MAB (eg, Cinqair, Fasenra, Nucala):**
    - Has asthma of an eosinophilic phenotype – Absolute blood eosinophil count: \_\_\_\_\_/ml    Date obtained: \_\_\_\_\_
    - Has severe asthma
  - For treatment of chronic idiopathic urticaria:**
    - Has a history of urticaria for a period of  $\geq 3$  months
    - Requires use of steroid to control urticarial symptoms

- Has a history of trial and failure of or contraindication or intolerance to all of the following at maximal tolerated doses (*check all that apply*):
- |   |  |
|---|--|
| <input type="checkbox"/> H <sub>1</sub> antihistamine | <input type="checkbox"/> leukotriene modifier                          |
| <input type="checkbox"/> H <sub>2</sub> antihistamine | <input type="checkbox"/> dapsone, sulfasalazine, or hydroxychloroquine |

**For treatment of EGPA:**

- Has a history of asthma and an absolute blood eosinophil count  $\geq 1000$ /microliter
- Has a history of asthma and a blood eosinophil level  $> 10\%$  of leukocytes
- Has evidence of the following (*check all that apply*):
- |   |   |
|---|---|
| <input type="checkbox"/> histopathological evidence of:                       | <input type="checkbox"/> sino-nasal abnormality |
| <input type="checkbox"/> eosinophilic vasculitis                              | <input type="checkbox"/> cardiomyopathy         |
| <input type="checkbox"/> perivascular eosinophilic infiltration               | <input type="checkbox"/> glomerulonephritis     |
| <input type="checkbox"/> eosinophil-rich granulomatous inflammation           | <input type="checkbox"/> alveolar hemorrhage    |
| <input type="checkbox"/> neuropathy (nerve deficit or conduction abnormality) | <input type="checkbox"/> palpable purpura       |
| <input type="checkbox"/> pulmonary infiltrates, non-fixed                     | <input type="checkbox"/> positive test for ANCA |
- Has a history of therapeutic failure of  $\geq 3$  months of prednisolone  $\geq 7.5$  mg/day (or equivalent) or has an intolerance or contraindication to systemic corticosteroids

**For Nucala (mepolizumab):**

- For a beneficiary  $\geq 50$  years of age:**
- Received the varicella-zoster vaccine (Shingrix/Zostavax) at least 4 weeks prior to initiation of Nucala

**RENEWAL requests**

Complete all sections applicable to the beneficiary and this request. Check all that apply and **SUBMIT DOCUMENTATION** for each item.

**For treatment of asthma:**

- Experienced measurable evidence of improvement in the severity of the asthma condition
- Will continue to use optimally titrated doses of, or has a contraindication or intolerance to, the following (*check all that apply*):
- |   |  |
|---|--|
| <input type="checkbox"/> inhaled glucocorticoid | <input type="checkbox"/> long-acting beta-agonist (LABA)             |
| <input type="checkbox"/> leukotriene modifier   | <input type="checkbox"/> other (eg, tiotropium, theophylline): _____ |

**For treatment of chronic idiopathic urticaria:**

- Experienced an improvement in symptoms
- Document rationale for continued use: \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

**For treatment of EGPA:**

- Experienced measurable evidence of improvement in disease activity

**PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION**

Prescriber Signature:

Date:

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