Gateway Health Plan
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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, hematologist/oncologist, rheumatologist, etc.); **AND**
6. If currently using a different MAB – Anti-IL, Anti-IgE than requested, will discontinue the other MAB – Anti-IL, Anti-IgE prior to starting the requested agent; **AND**
7. 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 MABs – 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

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 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

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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

9. 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;

AND

10. 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

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 control symptoms;
       ii. Has documented contraindication or intolerance of systemic glucocorticoids

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AND

12. 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**
13. For Cinqair (reslizumab) for a diagnosis of asthma with an eosinophilic phenotype, has an absolute blood eosinophil count ≥ 400 cells/microL; **AND**
14. For Nucala (mepolizumab) for a diagnosis of asthma, has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 150 cells/microL; **AND**
15. For Fasenra (benralizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count ≥ 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 (i.e., pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.); **AND**
3. Is not using the requested MAB – Anti-IL, Anti-IgE in combination with another MAB – Anti-IL, Anti-IgE; **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**

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7. For a diagnosis of HES, has documentation of **one** of the following:

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

   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.

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MONOCLONAL ANTIBODIES (MABs) – ANTI-IL, ANTI-IgE PRIOR AUTHORIZATION FORM

☐New request ☐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:

CLINICAL INFORMATION

Drug requested:	Strength:	Dosage form (pen, vial, etc):
Dose & directions:	Quantity:	Duration: _____ months
Diagnosis:	Dx code (*required*):	Weight: _____ lbs / kg

Has the beneficiary used the requested medication in the past 90 days? *Submit documentation.*	☐Yes – date of last dose: _____ ☐No
Is the requested medication being prescribed by or in consultation with a specialist?	☐Yes ☐No *Submit documentation of consultation, if applicable.*

INITIAL requests

For a non-preferred drug in this class: 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 https://papdl.com/preferred-drug-list for a list of preferred and non-preferred agents in this class.*	☐Yes ☐No *Submit documentation.*

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 SPONTANEOUS (IDIOPATHIC) URTICARIA:
- ☐Has a history of urticaria for a period of ≥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*):
  - ☐H_1 antihistamine
  - ☐H_2 antihistamine
  - ☐leukotriene modifier

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

☐ For treatment of HYPEREOSINOPHILIC SYNDROME (HES):
- ☐ Has documented FIP1L1-PDGFRA-negative HES
- ☐ Has organ damage or dysfunction
- ☐ Has a blood eosinophil count ≥1000/microliter
- ☐ Requires or has required systemic glucocorticoids to control symptoms
  - ☐ Has a contraindication or an intolerance to systemic glucocorticoids

☐ For treatment of nasal polyps:
- ☐ Has a history of trial and failure of or contraindication or intolerance to nasal corticosteroids
- ☐ For an anti-IgE MAB (eg, XOLAIR):
  - ☐ Has a serum total IgE measurement between 30 international units (IU)/mL and 1500 IU/mL

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*):
  - ☐ inhaled glucocorticoid
  - ☐ leukotriene modifier
  - ☐ long-acting beta-agonist (LABA)
  - ☐ other (eg, tiotropium, theophylline): _____

☐ For treatment of CHRONIC SPONTANEOUS (IDIOPATHIC) URTICARIA:
- ☐ Experienced an improvement in symptoms
- ☐ Document rationale for continued use: _____

_____

_____

☐ For treatment of EGPA:
- ☐ Experienced measurable evidence of improvement in disease activity

☐ For treatment of HYPEREOSINOPHILIC SYNDROME (HES):
- ☐ Experienced measurable improvement in disease activity
- ☐ Reduced use of systemic glucocorticoids for the treatment of HES

PLEASE FAX COMPLETED FORM TO GATEWAY – PHARMACY DIVISION

Prescriber Signature:	Date: