curative

Interleukin-5 (IL-5) Inhibitors Prior Authorization

Drug(s) Applied:	**Fasenra** (benralizumab)**, Nucala** (mepolizumab)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for an FDA approved indication and all of the following criteria are met:

I. Initial Therapy Criteria
- **A. Severe eosinophilic asthma** as indicated by chart notes within past 180 days
  1. Diagnosis confirmed by at least ONE of the following:
     a) Baseline (prior to therapy with the requested agent) blood eosinophilic count of 300 cells/microliter or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
     b) Fraction of exhaled nitric oxide (FeNO) of 20 parts per billion or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **or**
     c) Sputum eosinophils 2% or higher while on high-dose inhaled corticosteroids or daily oral corticosteroids **and**
  2. Patient has a history of uncontrolled asthma while on asthma controller therapy as demonstrated by ONE of the following:
     a) Frequent severe asthma exacerbations requiring two or more courses of systemic corticosteroids (steroid burst) within the past 12 months **or**
     b) Serious asthma exacerbations requiring hospitalization, mechanical ventilation, or visit to the emergency room or urgent care within the past 12 months **or**
     c) Controlled asthma that worsens when the doses of inhaled and/or systemic corticosteroids are tapered **or**
     d) Baseline (prior to therapy with the requested agent) Forced Expiratory Volume (FEV1) that is less than 80% of predicted **and**
  3. Patient is at least 6 years of age **and**
  4. Requested drug is not being used for the relief of acute bronchospasm or status asthmaticus **and**
  5. ONE of the following:
     a) Patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 consecutive months **or**
     b) Patient has an intolerance or FDA labeled contraindication to ALL inhaled corticosteroids **and**

6. ONE of the following:
    a) Patient is currently being treated for at least 3 consecutive months with a maximally tolerated long-acting beta-2 agonist (LABA) **or**
    b) Patient has an intolerance or FDA labeled contraindication to ALL inhaled LABAs **and**
7. ONE of the following:
    a) Patient has tried and had an inadequate response after a minimum of 3 consecutive months with a long-acting muscarinic antagonist (LAMA) **or**
    b) Patient has an intolerance to therapy with LAMAs **or**
    c) Patient has an FDA labeled contraindication to LAMAs **and**
8. ONE of the following:
    a) Patient is currently being treated for at least 3 consecutive months with ONE of the following:
        (1) Leukotriene receptor antagonist (LTRA) **or**
        (2) Oral corticosteroids (OCS) **or**
    b) Patient has an intolerance or hypersensitivity to therapy with LTRA or OCS **or**
    c) Patient has an FDA labeled contraindication to ALL LTRA and OCS **and**
9. Patient will continue asthma controller therapy (e.g., ICS, ICS/LABA, LAMA LTRA, LM, OCS) in combination with the requested agent **and**
10. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology, pulmonology) **and**
11. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

B. Eosinophilic granulomatosis with polyangiitis (EGPA) as indicated by chart notes within past 180 days

1. Patient is at least 18 years old **and**
2. Patient has had diagnosis of EGPA for at least 6 months with a history of relapsing or refractory disease **and**
3. Diagnosis confirmed by at least ONE of the following:
    a) Patient meets 4 of the following:
        (1) Asthma (history of wheezing or diffuse high-pitched rales on expiration)

(2) Eosinophilia (greater than 10% eosinophils on white blood cell differential count)
(3) Mononeuropathy (including multiplex), multiple mononeuropathies, or polyneuropathy attributed to a systemic vasculitis
(4) Migratory or transient pulmonary infiltrates detected radiographically
(5) Paranasal sinus abnormality
(6) Biopsy containing a blood vessel showing the accumulation of eosinophils in extravascular areas **or**

b) Patient meets ALL of the following:
(1) Medical history of asthma **and**
(2) Peak peripheral blood eosinophilia greater than 1000 cells/microliter **and**
(3) Systemic vasculitis involving two or more extra-pulmonary organs **and**

4. ONE of the following:
   a) Patient is currently on maximally tolerated oral corticosteroid therapy **or**
   b) Patient has an intolerance to oral corticosteroid therapy **or**
   c) Patient has an FDA labeled contraindication to ALL oral corticosteroids **and**
5. ONE of the following:
   a) Patient has tried and had an inadequate response to ONE non-corticosteroid immunosuppressant (e.g., azathioprine, cyclophosphamide, methotrexate, mycophenolate mofetil, leflunomide, rituximab) **or**
   b) Patient has an intolerance to ONE non-corticosteroid immunosuppressant **or**
   c) Patient has an FDA labeled contraindication to ALL of the following immunosuppressants: azathioprine, cyclophosphamide, methotrexate, and mycophenolate mofetil **and**
6. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., pulmonology, otolaryngology) **and**
7. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

C. **Hypereosinophilic syndrome (HES)** as indicated by chart notes within past 6 months
   1. Requested drug is Nucala **and**
   2. Patient has had diagnosis of HES for at least 6 months with a history of at least 2 HES flares within the past 12 months (i.e., worsening of clinical symptoms and/or blood eosinophil counts requiring an escalation in therapy) **and**
   3. Diagnosis confirmed by ALL of the following:
      a) Sustained eosinophil count (greater than 1500 cells/microliter and greater than or equal to 10% eosinophils for more than 4 weeks) **and**
      b) Secondary (reactive, non-hematologic) causes of eosinophilia have been excluded (e.g., infection, allergy/atopy, medications, collagen vascular disease, metabolic [e.g., adrenal insufficiency], solid tumor/lymphoma) **and**
      c) Documented evaluation of hypereosinophilia-related organ involvement (e.g., fibrosis of lung, heart, digestive tract, skin; thrombosis with or without thromboembolism; cutaneous erythema, edema/angioedema, ulceration, pruritis, or eczema; peripheral or central neuropathy with chronic or recurrent neurologic deficit; other organ system involvement such as liver, pancreas, kidney) **and**
      d) Patient does NOT have FIP1L1-PDGFRA-positive disease, pre-existing helminth infections, or non-hematologic secondary HES **and**
   4. Patient is at least 12 years of age **and**
   5. ONE of the following:
      a) Patient is currently being treated with maximally tolerated oral corticosteroid (OCS) for a minimum duration of 4 consecutive weeks **or**
      b) Patient has an intolerance to OCS therapy **or**
      c) Patient has an FDA labeled contraindication to ALL OCS **and**
   6. ONE of the following:
      a) Patient is currently being treated with either hydroxyurea, interferon-a, or immunosuppressive agent (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) for a minimum duration of 4 consecutive weeks **or**
      b) Patient has an intolerance to therapy with hydroxyurea, interferon-a, or immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **or**
      c) Patient has an FDA labeled contraindication to hydroxyurea, interferon-a, and ALL immunosuppressive agents (e.g., azathioprine, cyclosporine, methotrexate, tacrolimus) **and**

7. Patient will continue existing HES therapy (e.g., OCS, hydroxyurea, interferon-a, immunosuppressants) in combination with the requested agent **and**
8. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology) **and**
9. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

D. Chronic rhinosinusitis with nasal polyposis (CRSwNP) as indicated by chart notes within past 180 days

1. Requested drug is Nucala **and**
2. Patient is at least 18 years of age **and**
3. Patient has at least TWO of the following symptoms consistent with chronic rhinosinusitis (CRS) for at least 12 consecutive weeks::
    a) Nasal discharge (rhinorrhea or post-nasal drainage)
    b) Nasal obstruction or congestion
    c) Loss or decreased sense of smell (hyposmia)
    d) Facial pressure or pain **and**
4. Patient's diagnosis was confirmed by either anterior rhinoscopy or endoscopy, or computed tomography (CT) of the sinuses **and**
5. ONE of the following:
    a) Patient had an inadequate response to sinonasal surgery or is NOT a candidate for sinonasal surgery **or**
    b) ONE of the following:
        (1) Patient has tried and had an inadequate response to oral systemic corticosteroids **or**
        (2) Patient has an intolerance to therapy with oral systemic corticosteroids **or**
        (3) Patient has an FDA labeled contraindication to ALL oral systemic corticosteroids **and**
6. ONE of the following:
    a) Patient has tried and had an inadequate response to intranasal corticosteroids (e.g., fluticasone, mometasone, Sinuva) for a minimum of 4-week duration of therapy **or**
    b) Patient has an intolerance to therapy with intranasal corticosteroids **or**

c) Patient has an FDA labeled contraindication to ALL intranasal corticosteroids **and**

7. Patient is currently treated with standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) **and**
8. Patient will continue standard nasal polyp maintenance therapy in combination with the requested agent **and**
9. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology, otolaryngology) **and**
10. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

E. Inadequately controlled COPD and eosinophilic phenotype as indicated by chart notes within past 180 days

1. The requested drug is Nucala **and**
2. Patient is at least 18 years old **and**
3. Patient has at least a 12 month history of uncontrolled COPD while on COPD controller therapy as demonstrated by ALL of the following:
   a) At least 2 moderate (requiring treatment with either systemic corticosteroids and/or antibiotics) or 1 severe (requiring hospitalization) COPD exacerbation within the past 12 months **and**
   b) Blood eosinophil count of at least 150 cells/uL at screening or at least 300 cells/uL in the past 12 months **and**
   c) Patient has post-bronchodilator FEV1/FVC ratio <0.7 **and**
   d) Patient has post-bronchodilator FEV1 of 20% to 80% predicted **and**
4. BOTH of the following:
   a) Patient is currently treated with a maximally tolerated inhaled triple therapy for COPD (inhaled corticosteroid (ICS) + long-acting beta-2 agonist (LABA) + long-acting muscarinic antagonist (LAMA)) for at least 3 consecutive months **and**
   b) Patient will continue COPD controller therapy (e.g. ICS + LABA + LAMA) in combination with the requested agent **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology, pulmonology) **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be

using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 6 months

II. Continued Therapy Criteria

A. Severe eosinophilic asthma as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit from baseline (i.e., improvements or stabilization) as indicated by ONE of the following:
    a) Increase in percent predicted Forced Expiratory Volume (FEV1) **or**
    b) Decrease in the dose of inhaled corticosteroids required to control the patient's asthma **or**
    c) Decrease in need for treatment with systemic corticosteroids due to exacerbations of asthma **or**
    d) Decrease in number of hospitalizations, need for mechanical ventilation, or visits to urgent care or emergency room due to exacerbations of asthma **and**
3. ONE of the following:
    a) Patient is currently treated with an inhaled corticosteroid for at least 3 consecutive months that is adequately dosed to control symptoms **or**
    b) Patient is currently treated with a maximally tolerated inhaled corticosteroid for at least 3 months **or**
    c) Patient has an intolerance or FDA labeled contraindication to ALL inhaled corticosteroids **and**
4. Patient is currently treated and is compliant with asthma controller therapy (i.e., inhaled corticosteroids [ICS], ICS/long-acting beta-2 agonist [ICS/LABA], leukotriene receptor antagonist [LTRA], long-acting muscarinic antagonist [LAMA]) **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology, pulmonology) **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested

(e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

B. Eosinophilic granulomatosis with polyangiitis (EGPA) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit from baseline (i.e., improvements or stabilization) as indicated by ONE of the following:
    a) Remission achieved with the requested agent **or**
    b) Decrease in oral corticosteroid maintenance dose required for control of symptoms related to EGPA **or**
    c) Decrease in hospitalization due to symptoms of EGPA **or**
    d) Dose of maintenance corticosteroid therapy and/or immunosuppressant therapy was not increased **and**
3. ONE of the following:
    a) Patient is currently treated and is compliant with maintenance therapy with oral corticosteroids **or**
    b) Patient has an intolerance to oral corticosteroid therapy **or**
    c) Patient has an FDA labeled contraindication to ALL oral corticosteroids **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., pulmonology and otolaryngology) **and**
5. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

C. Hypereosinophilic syndrome (HES) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Requested agent is Nucala **and**
3. Documented clinical benefit from baseline (i.e., improvements or stabilization) as indicated by ONE of the following:
    a) Decrease in incidence of HES flares **or**
    b) Escalation of therapy (due to HES-related worsening of clinical

symptoms or increased blood eosinophil counts) has not been required **and**

4. ONE of the following:
    a) Patient is currently treated and is compliant with oral corticosteroid and/or other maintenance therapy (e.g., hydroxyurea, interferon-a, azathioprine, cyclosporine, methotrexate, tacrolimus) **or**
    b) Patient has an intolerance to therapy with oral corticosteroids or other maintenance agents (e.g., hydroxyurea, interferon-a, azathioprine, cyclosporine, methotrexate, tacrolimus) **or**
    c) Patient has an FDA labeled contraindication to ALL oral corticosteroids AND maintenance agents (e.g., hydroxyurea, interferon-a, azathioprine, cyclosporine, methotrexate, tacrolimus) **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology) **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

D. Chronic rhinosinusitis with nasal polyposis (CRSwNP) as indicated by chart notes within past 12 months

1. Patient meets the initial therapy criteria above **and**
2. Requested agent is Nucala **and**
3. Documented clinical benefit from baseline (i.e., improvement of nasal polyp symptom severity and improvement of nasal obstruction severity) **and**
4. Patient will continue standard nasal polyp maintenance therapy (e.g., nasal saline irrigation, intranasal corticosteroids) in combination with the requested agent **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology, otolaryngology) **and**
6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

E. **Inadequately controlled COPD and eosinophilic phenotype** as indicated by chart notes within past 12 months
    1. Requested agent is Nucala **and**
    2. Patient meets the initial therapy criteria above **and**
    3. Documented clinical benefit from baseline (i.e., reduction of moderate or severe COPD exacerbations) **and**
    4. Patient continues to be treated with and has greater than or equal to 80% adherence to maximally tolerated inhaled triple therapy for COPD (inhaled corticosteroid (ICS) + long-acting beta-2 agonist (LABA) + long-acting muscarinic antagonist (LAMA)) (provider attestation) **and**
    5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., allergy and immunology, pulmonology) **and**
    6. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required])

Approval Duration: 12 months

Policy Owned by: Curative PBM team