Mepolizumab (Nucala)

Severe Asthma Coverage Criteria:

1. Prescribed by an asthma specialist, allergist or pulmonologist; and,
2. Patient is ≥ 6 years of age and has a pre-treatment serum eosinophil count of 150 cells/mcL or greater at screening (within the previous 6 weeks); and,
3. Patient has inadequate asthma control (see criteria #4) despite the following standard therapies:
   a. Regular use of inhaled steroids (such as Flovent); and,
   b. Regular use of a long-acting beta-agonist (such as Serevent); and,
   c. Regular or periodic use of oral steroids; and,
4. Inadequate asthma control despite standard therapies is defined as one of the following:
   a. At least 2 exacerbations requiring oral systemic corticosteroids in the last 12 months; or,
   b. At least 1 exacerbation treated in a hospital or requiring mechanical ventilation in the last 12 months; and,
5. Patient is not currently using another biologic therapy for the treatment of asthma such as Cinqair, Dupixent, Fasenra or Xolair; and,
6. Prescribed within the FDA approved dosing regimen.

Coverage Duration:

Initial authorizations and reauthorizations will be provided for 12 months

Renewal Criteria:

1. Patient has been seen by provider in the past 12 months; and,
2. Patient has been adherent to therapy; and,
3. Patient has not experienced unacceptable toxicity; and,
4. Patient has a clinically meaningful response to the medication as defined:
   a. Decreased frequency of exacerbations defined as:
      i. Improvement of asthma control, demonstrated by decreased use of oral or systemic corticosteroids; or,
      ii. Less frequent hospitalizations; or,
      iii. Reduced frequency of emergency department visits; or,
   b. Improvement in lung function measured in FEV1; and,
5. Patient is not currently using another biologic therapy for the treatment of asthma such as Cinqair, Dupixent, Fasenra or Xolair; and,
6. Nucala is prescribed within FDA approved dosing regimen

P&T Date: 4/5/2021
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Eosinophilic Granulomatosis with Polyangiitis Coverage Criteria:

1. Prescribed by an asthma specialist, allergist, pulmonologist or rheumatologist; and,
2. Patient is ≥ 18 years of age; and,
3. Patient is diagnosed with eosinophilic granulomatosis with polyangiitis (EGPA) with a history or presence of asthma with eosinophilia (>10% eosinophils on the differential white blood cell count) and at least two of the following additional features of EGPA
   a. A biopsy showing histopathological evidence of eosinophilic vasculitis defined as:
      i. Perivascular eosinophilic infiltration, or eosinophil-rich granulomatous; or,
      ii. ii. Inflammation; or,
   b. Neuropathy, mono or poly (motor deficit or nerve conduction abnormality); or,
   c. Pulmonary infiltrates, non-fixed; or,
   d. Sino-nasal abnormality; or,
   e. Cardiomyopathy (established by echocardiography or MRI); or,
   f. Glomerulonephritis (hematuria, red cell casts or proteinuria); or,
   g. Alveolar hemorrhage (by bronchoalveolar lavage); or,
   h. Palpable purpura
      i. Positive test for ANCA (MPO or PR3); and,
4. Patient has tried and failed azathioprine or cyclophosphamide or methotrexate. Treatment failure is defined as one of the following:
   a. EGPA flare requiring oral corticosteroid (OCS) dose increase or hospitalization; or,
   b. EGPA symptom recurrence while tapering OCS dose; or,
   c. Patient has contraindications or it is clinically inappropriate to use all immunosuppressant options listed above; and
5. Prescribed within FDA approved dosing regimen.

Coverage Duration:

Initial authorizations will be provided for 6 months.
Reauthorizations will be provided for 12 months

Renewal Criteria:

1. Patient has been seen by provider within the past 12 months; and,
2. Patient has been adherent to therapy; and,
3. Patient has a clinically meaningful response to the medication as defined:
   a. Prednisolone or prednisone dose less than or equal to 4 mg/day; or
   b. Remission: Prednisolone dose ≤7.5 mg/day (or equivalent OCS) and BVAS = 0 4.
4. Nucala is prescribed within the FDA-approved dosing regimen.

Hypereosinophilic Syndrome (HES) Coverage Criteria:

1. Prescribed by a specialist with experience in treating patients with hypereosinophilic syndrome (such as an allergist, immunologist, pulmonologist); and,
2. A pre-treatment serum eosinophil count of 1,000 cells/mcL or greater at screening (within the previous 4 weeks); and,
3. Patient has had hypereosinophilic syndrome (HES) for at least 6 months; and
4. Provider attests the patient's HES is without an identifiable non-hematologic secondary cause (such as drug hypersensitivity, parasitic helminth infection, HIV infection, non-hematologic malignancy); and,
5. Patient has been on a stable dose of HES therapy (e.g., oral corticosteroid, immunosuppressive, and/or cytotoxic therapy); and,
6. Nucala is prescribed within the FDA-approved dosing regimen

Coverage Duration:

Initial authorizations will be provided for 6 months.
Reauthorizations will be provided for 12 months

Renewal Criteria:

1. Patient has been seen by the specialist within the past 12 months; and,
2. Patient has been adherent to therapy, and,
3. Patient has had a clinically meaningful response to the medication (decrease in hypereosinophilic syndrome flares) documented in the medical record; and,
4. Nucala is prescribed within the FDA-approved dosing regimen.

Nasal Polyps Coverage Criteria:

1. Patient is diagnosed with bilateral nasal polyposis and chronic symptoms of sinusitis; **and,**
2. Prescribed by or in consultation with an allergist, otolaryngologist or pulmonologist; **and,**
3. Patient has tried and failed intranasal corticosteroids for at least 3 months; **and,**
4. Patient has a documented reoccurrence of nasal polyps within 12 months of surgery to treat nasal polyps or a contraindication to surgical intervention; **and,**
5. Patient has moderate to severe symptoms defined as one of the following lasting greater than 12 weeks:
    a. Anterior or posterior rhinorrhea; **or,**
    b. Nasal congestion; **or,**
    c. Reduction or loss of smell; **or,**
    d. Nasal obstruction; **and,**
6. The member will use a daily intranasal corticosteroid concomitantly with Nucala; **and,**

7. Patient is not currently prescribed another biologic therapy for the treatment of nasal polyposis; **and,**
8. Nucala is prescribed within the FDA-approved dosing regimen.

Coverage Duration:

Initial authorizations will be provided for 6 months.
Reauthorizations will be provided for 12 months

Renewal Criteria:

1. Patient has been seen by the provider within the past 12 months**; and,**
2. Provider attests patient has achieved clinical benefit from use of Nucala for symptoms of chronic rhinosinusitis with nasal polyps**; and,**
3. Nucala continues to be prescribed within the FDA approved dosing regimen.