OPTIMA HEALTH PLAN

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-844-723-2094**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is NOT complete, correct, or legible, authorization will be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: Nucala™ SQ (mepolizumab) **(J2182) (Medical)**
{Eosinophilic Granulomatosis Polyangiitis (EGPA)}

DRUG INFORMATION: Complete **ALL** information below or authorization will be delayed.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

RECOMMENDED DOSAGE:

300mg SubQ once every 4 weeks administered as 3 separate 100-mg injections

CLINICAL CRITERIA: All criteria **MUST** be me to qualify for approval. Chart notes, including labs, **MUST** be submitted with this request or authorization will be delayed.

Initial Approval Length - 12 months

- ❑ Medication must be prescribed by an allergist, immunologist, or pulmonologist; **AND**
- ❑ Member must be 18 years of age or older; **AND**
- ❑ Member must have diagnosis of Eosinophilic Granulomatosis with Polyangiitis (EGPA) (Churg-Strauss Syndrome) > 6 months based on the history or presence of asthma; **AND**
  - ❑ Eosinophilia >10% **(must submit labs for documentation)**; **AND**
- ❑ Member must have documentation of **TWO** of the following **(chart notes/labs/diagnostics must be submitted for documentation)**:
  - ❑ A biopsy showing evidence of EGPA
  - ❑ Mono-or polyneuropathy
  - ❑ Pulmonary infiltrates, non-fixed on chest x-rays
  - ❑ Sino-nasal abnormality
  - ❑ Magnetic Resonance Imaging or Echocardiography of cardiomyopathy
  - ❑ Glomerulonephritis

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- ❑ Alveolar hemorrhage (by bronchoalveloar lavage)
- ❑ Palpable purpura
- ❑ Anti-neutrophil cytoplasmic anti-body (ANCA) positive (Myeloperoxidase or proteinase 3)

AND

- ❑ History of relapsing **OR** refractory disease defined as **(MUST select one of the following):**
  - ❑ **Relapsing disease:**
    - ❑ Must have a past history of at least one confirmed EGPA relapse requiring:
    - ❑ An increase in oral corticosteroids (OCS) dose
    - ❑ Initiation or increased dose of immunosuppressive therapy **(e.g., cyclophosphamide, methotrexate, azathioprine or mycophenolate mofetil)**
    - ❑ Hospitalization
  - ❑ Must have occurred > 12 weeks but < 2 years prior to initiation while receiving a dose of prednisone (or equivalent) of >7.5 milligram per day (mg/day) for **at least 90 consecutive days.**
  - ❑ **Refractory disease:**

    Either:
    - ❑ Failure to attain remission (Birmingham Vasculitis Activity Score (BVAS)=0) and OCS dose <7.5 mg/day prednisone or equivalent) for **at least 90 consecutive days** within the last 6 months following induction treatment with a standard regimen **(e.g., cyclophosphamide, methotrexate, azathioprine, mycophenolate mofetil, or high-dose corticosteroids** (> 15 mg/day prednisone), administered for at least 3 months.

      OR
    - ❑ Within 6 months prior to initiation, recurrence of symptoms of EGPA while tapering oral corticosteroids (OCS), occurring at any dose level ≥7.5 mg/day prednisone or equivalent taken for **at least 90 consecutive days.**

Current Exclusion Criteria: Exclusions (therapy will not be approved if member has history of any of the following):

- ❑ Organ/life threatening EGPA within 3 months prior to initiation
- ❑ Rituximab within the past year; IVIg within the past 6 months; omalizumab within the past 4 months
- ❑ Pregnancy, breast-feeding, absence of contraception if female of child-bearing age

Revised Exclusion Criteria:

- ❑ Organ/life threatening EGPA within 3 months prior to initiation
- ❑ Malignancy: current malignancy or previous history of cancer in remission for < 12 months

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- ❑ Unstable cardiovascular disease: Ejection fraction < 20%, New York Heart Association Class III/IV failure, acute myocardial infarction diagnosed less than 3 months
- ❑ Unstable liver disease: Presence of ascites, encephalopathy, coagulopathy, hypoalbuminemia, esophageal or gastric varices, cirrhosis, and known biliary abnormalities (with the exception of Gilbert's syndrome or asymptomatic gallstones.
- ❑ Rituximab within the past year; IVIg within the past 6 months; omalizumab within the past 4 months
- ❑ Pregnancy, breast-feeding, absence of contraception if female of child-bearing age

REAUTHORIZATION APPROVAL - 12 MONTHS

CLINICAL CRITERIA: **ALL** criteria **MUST** be met for approval. **ALL** documentation, including lab results and/or chart notes **(when required)**, **MUST** be provided or request will be denied.

- ❑ Documentation of remission or improvement in the Brimingham Vasculitis Activity Score (BVAS) or prednisone/prednisolone daily dose of ≤ 7.5mg

OR

- ❑ Documentation of decrease in maintenance dose of systemic corticosteroids, improvement in asthma symptoms or asthma exacerbations

OR

- ❑ Documentation of disease flares with tapering of corticosteroid therapy or immunotherapy

Medication being provided by a Specialty Pharmacy - PropriumRx

Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** ~~6/29/2018~~; 8/16/2018
REVISED/UPDATED: ~~12/30/2018;~~ **(Reformatted) 3/18/2019**