

OPTIMA HEALTH COMMUNITY CARE

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 1-844-348-3720. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.*

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

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

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

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

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

- 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) \geq 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
 - Alveolar hemorrhage (by bronchoalveolar 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 \geq 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.**

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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**.

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
- QTc(F) ≥ 450 msec (≥ 480 if bundle branch block)
- Malignancy (unless in remission for >1 year), unstable liver or cardiovascular disease
- 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

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: 2/15/2018

REVISED/UPDATED: 6/29/2018