

Mepolizumab (NUCALA) Criteria for Use

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. **THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.**

Exclusion Criteria (if ONE is checked, patient is not eligible)

- Prior allergic reaction to mepolizumab
- Acute exacerbation of asthma or status asthmaticus
- Currently treated with omalizumab (unless omalizumab to be discontinued when starting mepolizumab)
- Currently undergoing bronchial thermoplasty

Inclusion Criteria

- Provider is an asthma specialist (pulmonologist, allergist, immunologist)
- Diagnosis of asthma
- Receiving high-dose inhaled corticosteroid (or maximally tolerated dose) AND ≥ 3 months of a second controller drug (i.e. long-acting beta agonist, long-acting muscarinic antagonist, leukotriene receptor antagonist) \pm oral corticosteroid*
- Blood eosinophil ≥ 150 cells/ μ L obtained within previous 6 weeks prior to treatment
- Adherent to asthma medications as evidenced by a review of prescription refill history during the last 12 months

AND at least ONE of the following:

- ≥ 2 exacerbations requiring systemic corticosteroid OR ≥ 1 hospitalization due to asthma exacerbation in the prior year
- Requires maintenance oral steroids
- Inadequate symptom control (e.g., short-acting beta-agonist use > 2 days/week, nighttime awakening due to asthma > 1 time/week, limitation with normal activity, Asthma Control Test < 19)

**Providers should observe patient's inhaler use, as poor technique frequently is a cause of poor results in asthma*

Dosage and Administration

Please refer to Product Information for detailed information on preparation, dosage, and administration

Note: Mepolizumab should be reconstituted and administered by a healthcare professional. Mepolizumab is administered subcutaneously.

Issues for Consideration

Hypersensitivity reactions: Hypersensitivity reactions such as angioedema, bronchospasm, hypotension, urticaria, and rash have occurred following administration of mepolizumab. Generally, reactions occur within hours of administration, but in some instances can have a delayed onset of days. Discontinue mepolizumab in the event of a hypersensitivity reaction.

Herpes zoster: Two serious cases of herpes zoster occurred in patients treated with mepolizumab compared with none in the placebo group. Consider varicella vaccination, if medically appropriate, prior to starting therapy with mepolizumab.

Reduction of corticosteroid dosage: Do not abruptly discontinue systemic or inhaled steroids upon initiation of mepolizumab. If appropriate, reduction should be done gradually and under the care of a physician.

Parasitic (helminth) infection: It is unknown if mepolizumab will influence a patient's response against parasitic infections (patients with known parasitic infections were excluded from the clinical trials). Pre-existing infection should be treated prior to initiating therapy with mepolizumab. If an infection occurs while being treated with mepolizumab and does not respond to anti-helminth therapy, discontinue mepolizumab until infection resolves.

The mepolizumab studies included a majority of female patients (59%) and majority of white patients (85%). Genetics and hormonal differences play a large part in how patients respond to asthma therapy, and should be considered when starting mepolizumab.

In the clinical trials, patients who had previously received omalizumab were eligible for inclusion into the study if they had not received omalizumab for ≥ 130 days. The washout period was to avoid any potential carry over from omalizumab which has a

long half-life. There are no recommendations in the labeling requiring a waiting period before starting mepolizumab; however, providers should be aware of any potential adverse drug events.

Monitoring

Effectiveness of therapy should be evaluated within 6 months. Goal should be the objective improvement in selected markers of asthma control, such as symptoms severity, frequency of rescue treatments, oral steroid requirements, and frequency of urgent outpatient visits and/or hospitalization. This information should be used to determine continuation of therapy.

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