

EFFECTIVE DATE: 10|01|2016

POLICY LAST UPDATED: 09|06|2016

OVERVIEW

This policy documents coverage guidelines required for the use of Mepolizumab (Nucala). Mepolizumab is a treatment for severe asthma in appropriate patients.

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

Mepolizumab may be considered medically necessary when the following criteria are met:

1. Diagnosis of severe asthma **AND**
2. Asthma is an eosinophilic phenotype as defined by one of the following:
 - Baseline peripheral blood eosinophil levels are greater than or equal to 150 cells/microliter (provide documentation) **OR**
 - Peripheral blood eosinophil levels were greater than or equal to 300 cells/microliter within the past 12 months (provide documentation)

AND

3. One of the following:
 - Patient has had at least two or more asthma exacerbations requiring systemic corticosteroids within the past 12 months **OR**
 - Patient has had a prior asthma-related hospitalization within the past 12 months

AND

4. One of the following:
 - Patient's symptoms are inadequately controlled with high-dose inhaled corticosteroid (ICS) plus one or more other controller medications (e.g., LABA, leukotriene antagonist, anticholinergic) for at least 6 months and patient has been adherent to drug therapies **OR**
 - Patient is receiving a maximally-dosed combination ICS/LABA product [e.g., Advair (fluticasone propionate/salmeterol), Dulera (mometasone/formoterol), Symbicort (budesonide/formoterol)] for the past 6 months and patient has been adherent to drug therapies **AND**

5. Age greater than or equal to 12 years **AND**

6. Prescribed by or in consultation with a pulmonologist or an allergy/immunology specialist

AND

7. The patient will not receive the requested agent in combination with Xolair or with another interleukin 5 inhibitor (e.g. Cinqair).

Authorization for continued use shall be reviewed at 6 months and then every 12 months to confirm the following:

1. Patient has experienced an objective response to therapy, defined as one or more of the following for allergic asthma:
 - Reduction in number of asthma exacerbations from baseline (i.e., asthma exacerbation requiring treatment with systemic corticosteroids or doubling of ICS dose from baseline)
 - Improvement in forced expiratory volume in 1 second (FEV1) from baseline
 - Decreased use of rescue medications from baseline

PRIOR AUTHORIZATION

BlueCHiP for Medicare and Commercial Products

Prior authorization review is required for BlueCHiP for Medicare and recommended for Commercial products.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Mepolizumab therapy is medically necessary for BlueCHiP for Medicare and Commercial products when all of the above medical criteria are met.

COVERAGE

Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable Specialty Pharmacy guidelines.

Specialty Drug Coverage:

For contracts with specialty drug coverage, please refer to the member agreement for benefits and preauthorization guidelines.

BACKGROUND

Mepolizumab (Nucala) is used with other asthma medicines for the maintenance treatment of asthma in patients 12 years of age and older. Nucala is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines. Nucala reduces severe asthma attacks by reducing the levels of blood eosinophils, a type of white blood cell that contributes to the development of asthma.

Nucala is an interleukin-5 antagonist monoclonal antibody (IgG1 kappa) indicated for add-on maintenance treatment of patients with severe asthma 12 years of age and older, and with an eosinophilic phenotype. Nucala is not indicated for treatment of other eosinophilic conditions or for the relief of acute bronchospasm or status asthmaticus.

Nucala has been shown to decrease the incidence of asthma exacerbations in adult and adolescent patients 12 years of age and older with severe asthma whose symptoms are inadequately controlled with inhaled corticosteroids. Nucala is approved for patients who have a history of severe asthma attacks (exacerbations) despite receiving their current asthma medicines.

CODING

BlueCHiP for Medicare and Commercial Products

Claims should be filed with the appropriate NDC and an Unlisted HCPCS code.

RELATED POLICIES

Omalizumab (Xolair)
Reslizumab (Cinqair)

PUBLISHED

Provider Update, October 2016

REFERENCES

1. Nucala [package insert]. Philadelphia, PA: GlaxoSmithKline LLC.; November 2015.

[CLICK THE ENVELOPE ICON BELOW TO SUBMIT COMMENTS](#)

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's subscriber agreement or member certificate and/or the employer agreement, and those documents will supersede the provisions of this medical policy. For information on member-specific benefits, call the provider call center. If you provide services to a member which are determined to not be medically necessary (or in some cases medically necessary services which are non-covered benefits), you may not charge the member for the services unless you have informed the member and they have agreed in writing in advance to continue with the treatment at their own expense. Please refer to your participation agreement(s) for the applicable provisions. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. BCBSRI reserves the right to review and revise this policy for any reason and at any time, with or without notice. Blue Cross & Blue Shield of Rhode Island is an independent licensee of the Blue Cross and Blue Shield Association.

