MEPOLIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
MEPOLIZUMAB	NUCALA	42775		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome, **AND** meet the following criterion?
   - The patient is 18 years of age or older

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL with a quantity limit of #3 vials/syringes (300mg) per 28 days.**
   - **If the plan does NOT cover non-self-administered agents: Approve by GPID (46413 and 46414) with a quantity limit of #3 syringes (300mg) per 28 days.**

   APPROVAL TEXT: Renewal requires a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome.

   If no, continue to #2.

2. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient is 6 years of age or older
   - The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 6 weeks
   - The patient had a prior therapy with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, a long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
   - The patient has experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
   - Nucala will be used as add-on maintenance treatment
   - The patient is not concurrently treated with Xolair, Dupixent, or another anti-IL-5 asthma biologic (e.g., Cinqair, Fasenra)
   - Nucala is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

If yes, **approve for 12 months as follows:**

- **If the plan covers non-self-administered (NSA) agents: Approve by HICL with a quantity limit of #1 vial/syringe (100mg) per 28 days.**
- **If the plan does NOT cover non-self-administered agents: Approve by GPID (46413 and 46414) with a quantity limit of #1 syringe (100mg) per 28 days.**

APPROVAL TEXT: Renewal requires ALL of the following: i) the patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers, ii) the patient has shown a clinical response as evidenced by one of the following: a) reduction in asthma exacerbation from baseline, b) decreased utilization of rescue medications, c) increase in percent predicted FEV1 from pretreatment baseline, or d) reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.).

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **MEPOLIZUMAB (Nucala)** requires a diagnosis of severe asthma with an eosinophilic phenotype or eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome. In addition, the following criteria must be met:

For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), approval requires:

- The patient is 18 years of age or older

For the diagnosis of severe asthma with an eosinophilic phenotype, approval requires:

- The patient is 6 years of age or older
- The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 6 weeks
- The patient had a prior therapy with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist, a long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least ONE asthma exacerbation within the past 12 months (exacerbation is defined as an asthma-related event requiring hospitalization, emergency room visit, or systemic corticosteroid burst lasting at least 3 days)
- Nucala will be used as add-on maintenance treatment
- The patient is not concurrently treated with Xolair, Dupixent, or another anti-IL-5 asthma biologic (e.g., Cinqair, Fasenra)
- Nucala is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

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MEPOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome?

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL with a quantity limit of #3 vials/syringes (300mg) per 28 days.**
   - **If the plan does NOT cover non-self-administered agents: Approve by GPID (46413 and 46414) with a quantity limit of #3 syringes (300mg) per 28 days.**

   If no, continue to #2.

2. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
   - The patient has shown a clinical response as evidenced by **ONE** of the following:
     - Reduction in asthma exacerbation from baseline
     - Decreased utilization of rescue medications
     - Increase in percent predicted FEV1 from pretreatment baseline
     - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

   If yes, **approve for 12 months as follows:**
   - **If the plan covers non-self-administered (NSA) agents: Approve by HICL with a quantity limit of #1 vial/syringe (100mg) per 28 days.**
   - **If the plan does NOT cover non-self-administered agents: Approve by GPID (46413 and 46414) with a quantity limit of #1 syringe (100mg) per 28 days.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

RENEWAL DENIAL TEXT: The guideline named **MEPOLIZUMAB (Nucala)** requires a diagnosis of severe asthma with an eosinophilic phenotype or eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome. In addition, the following criteria must be met:
For the diagnosis of severe asthma with an eosinophilic phenotype, approval requires:

- The patient will continue to use inhaled corticosteroid (ICS) or ICS-containing combination inhalers
- The patient has shown a clinical response as evidenced by ONE of the following:
  - Reduction in asthma exacerbation from baseline
  - Decreased utilization of rescue medications
  - Increase in percent predicted FEV1 from pretreatment baseline
  - Reduction in severity or frequency of asthma-related symptoms (e.g., wheezing, shortness of breath, coughing, etc.)

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nucala.

REFERENCES

- Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline, LLC.; September 2019.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 11/15
Client Approval: 11/19
P&T Approval: 10/19