STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

MEPOLIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
MEPOLIZUMAB	NUCALA	42775		GPI-10 (4460405500)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. 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
   - Therapy is prescribed by or in consultation with a physician specializing in pulmonary medicine or allergy medicine
   - The patient has a documented blood eosinophil level of at least 150 cells/mcL within the past 12 months
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (ICS, e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, or oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL-5 biologic (e.g., Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

     If yes, continue to #2.
     If no, continue to #4.

2. Does the patient meet **ONE** of the following criteria?
   - The patient has experienced at least ONE asthma exacerbation requiring systemic corticosteroid burst lasting at least 3 days within the past 12 months
   - The patient has experienced at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months

     If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

     If no, continue to #3.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

3. Does the patient have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks?
   - Daytime asthma symptoms more than twice per week
   - Any night waking due to asthma
   - Use of a short-acting inhaled beta2-agonist reliever (SABA, e.g., albuterol) for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with an otolaryngologist or allergist/immunologist
   - Nucala will be used as add-on maintenance treatment
   - The patient had a 90-day trial of ONE intranasal corticosteroid (e.g., mometasone, fluticasone, beclomethasone)

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, continue to #5.

5. 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 by HICL or GPI-10 with a quantity limit of #3 vials/syringes per 28 days.**

   If no, continue to #6.

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

6. Does the patient have a diagnosis of hypereosinophilic syndrome (HES) and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - The patient has had HES for 6 months or more without an identifiable non-hematologic secondary cause

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #3 vials/syringes per 28 days.**

   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Severe asthma with an eosinophilic phenotype (type of lung condition with inflammation)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP: inflammation of nasal and sinus passages with small growths in the nose)
      3. Eosinophilic granulomatosis with polyangiitis (EGPA), also known as Churg-Strauss syndrome (inflammation of blood vessels with high levels of a type of white blood cell)
      4. Hypereosinophilic syndrome (HES) (a rare blood disorder)
   B. **If you have severe asthma with an eosinophilic phenotype, approval also requires:**
      1. You are 6 years of age or older
      2. Therapy is prescribed by or in consultation with a doctor specializing in pulmonary (lung/ breathing) medicine or allergy medicine
      3. You have a documented blood eosinophil (type of white blood cell) level of at least 150 cells/mcL within the past 12 months
      4. You are being treated with a medium, high-dose, or maximally tolerated dose of an inhaled corticosteroid (such as triamcinolone acetonide, beclomethasone, mometasone, budesonide) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or oral corticosteroid (such as prednisone)

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MEPOLIZUMAB

INITIAL CRITERIA (CONTINUED)

5. You meet ONE of the following:
   a. You experienced at least ONE asthma exacerbation (worsening of symptoms) requiring systemic corticosteroid (such as prednisone) burst lasting at least 3 days within the past 12 months OR at least ONE serious asthma exacerbation requiring hospitalization or emergency room visit within the past 12 months
   b. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
      i. Daytime asthma symptoms more than twice per week
      ii. Any night waking due to asthma
      iii. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
      iv. Any activity limitation due to asthma
6. You will NOT use Nucala concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL-5 biologic (such as Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

C. **If you have chronic rhinosinusitis with nasal polyps, approval also requires:**
   1. You are 18 years of age or older
   2. Therapy is prescribed by or in consultation with an otolaryngologist (ear, nose, and throat doctor) or allergist/immunologist (a type of allergy or immune system doctor)
   3. Nucala will be used as add-on maintenance treatment
   4. You had a 90-day trial of ONE intranasal corticosteroid (such as mometasone, fluticasone, beclomethasone)

D. **If you have eosinophilic granulomatosis with polyangiitis, approval also requires:**
   1. You are 18 years of age or older

E. **If you have hypereosinophilic syndrome, approval also requires:**
   1. You are 12 years of age or older
   2. You have had HES for 6 months or more without an identifiable non-hematologic (not present in the blood) secondary cause

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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MEPOLIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

NOTE: For the diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA, Churg-Strauss syndrome) OR hypereosinophilic syndrome (HES), please refer to the Initial Criteria section.

1. Does the patient have a diagnosis of severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient continues to use an inhaled corticosteroid (e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide) AND at least one other maintenance medication (e.g., a long-acting inhaled beta2-agonist [e.g., formoterol, salmeterol], a long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline, or oral corticosteroid [e.g., prednisone])
   - Nucala will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL-5 biologic (e.g., Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

     If yes, continue to #2.
     If no, continue to #3.

2. Has the patient shown a clinical response as evidenced by **ONE** of the following criteria?
   - 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 by HICL or GPI-10 with a quantity limit of #1 vial/syringe 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)

3. Does the patient have a diagnosis of chronic rhinosinusitis with nasal polyps (CRSwNP) **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline (e.g., improvements in nasal congestion, sense of smell or size of polyps)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 vial/syringe per 28 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **MEPOLIZUMAB (Nucala)** requires the following rule(s) be met for renewal:
   A. You have ONE of the following diagnoses:
      1. Severe asthma with an eosinophilic phenotype (type of lung condition with inflammation)
      2. Chronic rhinosinusitis with nasal polyps (CRSwNP; inflammation of nasal and sinus ways with small growths in the nose)
   B. **If you have severe asthma with an eosinophilic phenotype, renewal also requires:**
      1. You will continue to use an inhaled corticosteroid (such as triamcinolone acetonide, beclomethasone, mometasone, budesonide) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), a long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, tiotropium, umeclidinium), a leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or an oral corticosteroid (such as prednisone)
      2. You will NOT use Nucala concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL-5 biologic (such as Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma
      3. You have shown a clinical response as evidenced by ONE of the following:
         a. You have experienced a reduction in asthma exacerbation (worsening of symptoms) from baseline
         b. You have decreased use of rescue medications (such as albuterol)
         c. You have an increase in percent predicted FEV1 (amount of air you can forcefully exhale in one second) from pretreatment baseline (before starting Nucala)
         d. You have a reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

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MEPOLIZUMAB

RENEWAL CRITERIA (CONTINUED)

C. **If you have chronic rhinosinusitis with nasal polyposis, renewal also requires:**
   1. You have had a clinical benefit compared to baseline (before starting Nucala) (such as improvements in nasal congestion, sense of smell or size of polyps)

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

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

REFERENCES

- Nucala [Prescribing Information]. Philadelphia, PA: GlaxoSmithKline, LLC.; March 2023.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 06/01/23

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