STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TEZEPELUMAB-EKKO

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZEPELUMAB-EKKO	TEZSPIRE	47740		GPI-10 (4460807525)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of severe asthma and meet **ALL** of the following criteria?
   - The patient is 12 years of age or older
   - Therapy is prescribed by or in consultation with a physician specializing in allergy or pulmonary medicine
   - The patient is concurrently treated with a medium, high-dose, or maximally tolerated inhaled corticosteroid (ICS) [e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium], leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Tezspire will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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, continue to #4.
   If no, continue to #3.

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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 (SABA) [e.g., albuterol] reliever for symptoms more than twice per week
   - Any activity limitation due to asthma

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have severe asthma with an eosinophilic phenotype and meet **ALL** of the following criteria?
   - The patient has a documented blood eosinophil level of at least 150 cells/mcL within the last 12 months
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, continue to #5.

5. Does the patient have severe oral corticosteroid-dependent asthma **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the following preferred agent: Dupixent (dupilumab)

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, continue to #6.

6. Does the patient have severe allergic asthma **AND** meet the following criterion?
   - The patient had a trial of or contraindication to the following preferred agent: Xolair (omalizumab)

   If yes, **approve for 4 months by HICL or GPI-10 with a quantity limit of #1.91mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

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 **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for approval:

A. You have severe asthma (a type of lung condition)
B. You are 12 years of age or older
C. Therapy is prescribed by or in consultation with a doctor specializing in allergy or pulmonary (lung/breathing) medicine
D. You are being treated with a medium, high-dose, or maximally tolerated 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 salmeterol, formoterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), or theophylline
E. You meet ONE of the following:
    1. 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
    2. You have poor symptom control despite current therapy as evidenced by at least THREE of the following within the past 4 weeks:
        a. Daytime asthma symptoms more than twice per week
        b. Any night waking due to asthma
        c. Use of a short-acting inhaled beta2-agonist reliever (such as albuterol) for symptoms more than twice per week
        d. Any activity limitation due to asthma
F. You will NOT use Tezspire concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma
G. **If you have severe asthma with an eosinophilic phenotype (type of inflammatory asthma), approval also requires:**
    1. You have a documented blood eosinophil (a type of white blood cell) level of at least 150 cells/mcL within the last 12 months
    2. You had a trial of or contraindication (harmful for) to TWO of the following: Fasenra (benralizumab), Nucala (mepolizumab), Dupixent (dupilumab)

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TEZEPELUMAB-EKKO

INITIAL CRITERIA (CONTINUED)

H. **If you have severe oral corticosteroid-dependent asthma, approval also requires:**
   1. You had a trial of or contraindication (harmful for) to Dupixent (dupilumab)

I. **If you have severe allergic asthma, approval also requires:**
   1. You had a trial of or contraindication (harmful for) to Xolair (omalizumab)

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.

RENEWAL CRITERIA

1. Has the patient shown a clinical response as evidenced by **ONE** of the following?
   - Reduction in asthma exacerbation from baseline
   - Decreased utilization of rescue medications (e.g., albuterol)
   - 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, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
   - The patient will continue to use an inhaled corticosteroid (ICS) [e.g., triamcinolone acetonide, beclomethasone, mometasone, budesonide] AND at least one other maintenance medication (e.g., long-acting inhaled beta2-agonist [e.g., salmeterol, formoterol], long-acting muscarinic antagonist [e.g., aclidinium bromide, ipratropium, tiotropium, umeclidinium], a leukotriene receptor antagonist [e.g., montelukast, zafirlukast, zileuton], theophylline)
   - Tezspire will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1.91mL 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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TEZEPELUMAB-EKKO

RENEWAL CRITERIA (CONTINUED)

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 **TEZEPELUMAB-EKKO (Tezspire)** requires the following rule(s) be met for renewal:

A. You have shown a clinical response as evidenced by ONE of the following:
   1. Reduction in asthma exacerbation (worsening of symptoms) from baseline
   2. Decreased use of rescue medications (such as albuterol)
   3. Increase in percent predicted FEV1 (amount of air exhaled in one second) from pretreatment baseline
   4. Reduction in severity or frequency of asthma-related symptoms (such as wheezing, shortness of breath, coughing)

B. You will continue to use an inhaled corticosteroid (such as triamcinolone acetonide, beclomethasone) AND at least one other maintenance medication such as a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as ipratropium, tiotropium), leukotriene receptor antagonist (such as montelukast, zafirlukast), or theophylline

C. You will NOT use Tezspire concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or an anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab], Fasenra [benralizumab]) when used for the treatment of asthma

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 Tezspire.

REFERENCES

- Tezspire [Prescribing Information]. Thousand Oaks, CA: Amgen, Inc.; February 2023.

Library	Commercial	NSA
Yes	Yes	Yes

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