STANDARD COMMERCIAL AND NSA DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BENRALIZUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BENRALIZUMAB	FASENRA	44635		GPI-10 (4460402000)	

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 12 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], 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])
   - Fasenra will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab]) 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.

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

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 a total of 4 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 2 months with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 2 months with a quantity limit of #1mL per 56 days. (Start date is 1 week before the end of the first approval.)**

   If no, continue to #3.

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 a week
   - Any activity limitation due to asthma

   If yes, **approve for a total of 4 months by HICL or GPI-10 as follows:**
   - **FIRST APPROVAL: approve for 2 months with a quantity limit of #1mL per 28 days.**
   - **SECOND APPROVAL: approve for 2 months with a quantity limit of #1mL per 56 days. (Start date is 1 week before the end of the first approval.)**

   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 **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for approval:
   A. You have severe asthma with an eosinophilic phenotype (type of lung condition with inflammation)
   B. You are 12 years of age or older
   C. Therapy is prescribed by or in consultation with a physician specializing in pulmonary (lung/breathing) medicine or allergy medicine
   (Initial denial text continued on next page)

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

D. You have a documented blood eosinophil level (type of white blood cell) of at least 150 cells/mcL within the past 12 months
E. You are being treated with a medium, high-dose, or a maximally tolerated dose of an inhaled corticosteroid (such as triamcinolone acetonide, beclomethasone, mometasone, budesonide) AND at least one other maintenance medication which includes a long-acting inhaled beta2-agonist (such as formoterol, salmeterol), long-acting muscarinic antagonist (such as aclidinium bromide, ipratropium, umeclidinium, tiotropium), leukotriene receptor antagonist (such as montelukast, zafirlukast, zileuton), theophylline, or oral corticosteroid (such as prednisone)
F. 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 a 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 a week
        d. Any activity limitation due to asthma
G. You will NOT use Fasenra concurrently (at the same time) with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL5 biologic (such as Nucala [mepolizumab], Cinqair [reslizumab]) 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.

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BENRALIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. 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., 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])
   - Fasenra will NOT be used concurrently with Xolair (omalizumab), Dupixent (dupilumab), or another anti-IL5 biologic (e.g., Nucala [mepolizumab], Cinqair [reslizumab]) when used for the treatment of asthma

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

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)

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1mL per 56 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 **BENRALIZUMAB (Fasenra)** requires the following rule(s) be met for renewal:
   A. 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)

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BENRALIZUMAB

RENEWAL CRITERIA (CONTINUED)

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

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 Fasenra.

REFERENCES

- Fasenra [Prescribing Information]. Wilmington, DE: AstraZeneca Pharmaceutical LP.; February 2021.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
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