BENRALIZUMAB

Generic	Brand	HICL	GCN	Exception/Other
BENRALIZUMAB	FASENRA	44635		

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
    - 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, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
    - The patient has experienced at least **ONE** asthma exacerbations 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 or more days)
    - Fasenra will be used as add-on maintenance treatment
    - The patient is NOT being concurrently treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (e.g. Nucala, Cinqair)
    - Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

    If yes, **please approve as follows:**
    - **If the plan covers non-self-administered (NSA) agents: Approve by HICL and enter TWO approvals as below:**
        - **FIRST APPROVAL: approve for 12 weeks (total fill count of 3) with a quantity limit of 1mL (one 30mg/mL pre-filled syringe/autoinjector pen) per 28 days.**
        - **SECOND APPROVAL: approve for 40 weeks (total fill count of 5) with a quantity limit of 1mL (one 30mg/mL pre-filled syringe/autoinjector pen) per 56 days.**
    - **If the plan does NOT cover non-self-administered agents: Approve by GPID and enter TWO approvals as below:**
        - **FIRST APPROVAL: approve for 12 weeks (total fill count of 3) with a quantity limit of 1mL (one 30mg/mL autoinjector pen) per 28 days.**
        - **SECOND APPROVAL: approve for 40 weeks (total fill count of 5) with a quantity limit of 1mL (one 30mg/mL autoinjector pen) per 56 days.**

    APPROVAL TEXT: See initial approval text on the next page.

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BENRALIZUMAB

INITIAL CRITERIA (CONTINUED)

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 **BENRALIZUMAB (Fasenra)** requires a diagnosis of severe asthma with an eosinophilic phenotype. In addition, the following criteria must be met:

- The patient is 12 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, long-acting muscarinic antagonist, a leukotriene receptor antagonist, theophylline, or oral corticosteroid)
- The patient has experienced at least **ONE** asthma exacerbations 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 or more days)
- Fasenra will be used as add-on maintenance treatment
- The patient is NOT being concurrently treated with Xolair, Dupixent, or another anti-IL5 asthma biologic (e.g. Nucala, Cinqair)
- Fasenra is prescribed by or given in consultation with a physician specializing in pulmonary medicine or allergy medicine

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BENRALIZUMAB

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. 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 1mL (one 30mg/mL pre-filled syringe/autoinjector pen) per 56 days.**
   - **If the plan does NOT cover non-self-administered agents: Approve by GPID with a quantity limit of 1mL (one 30mg/mL autoinjector pen) per 56 days.**

   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **BENRALIZUMAB (Fasenra)** requires a diagnosis of severe asthma with an eosinophilic phenotype. In addition, the following criteria must be met:
   - 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 Fasenra

REFERENCES

- Fasenra [Prescribing Information]. Wilmington, DE. AstraZeneca Pharmaceutical LP. October 2019.

Library	Commercial	NSA
Yes	Yes	Yes

Part D Effective: N/A
Commercial Effective: 01/01/20
Created: 02/18
Client Approval: 11/19
P&T Approval: 10/19

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