Afrezza

Description

Afrezza (insulin human)

Background
Afrezza (insulin human) Inhalation Powder is a rapid-acting inhaled insulin to improve glycemic control in adults with diabetes mellitus. Afrezza is a rapid-acting inhaled insulin that is administered at the beginning of each meal. Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes (1).

Regulatory status
FDA Approved Indications: Afrezza is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus (1).

Limitations of Use (1):
- In patients with type 1 diabetes, must use with a long-acting insulin.
- Not recommended for the treatment of diabetic ketoacidosis.
- Not recommended in patients who smoke.

Afrezza carries a boxed warning regarding the risk of acute bronchospasm in patients with chronic lung disease. Afrezza is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD). Before initiating therapy with Afrezza, evaluate all patients with a detailed medical history, physical examination, and spirometry (FEV₁) to identify potential lung disease. Spirometry (FEV₁) should also be assessed after the first 6 months of therapy, and annually thereafter, even in the absence of pulmonary
symptoms. In patients who have a decline of $\geq 20\%$ in FEV$_1$ from baseline, consider discontinuing Afrezza (1).

The use of Afrezza during episodes of hypoglycemia is contraindicated. Hypoglycemia is the most common adverse reaction associated with insulin’s, including Afrezza (1).

Safety and effectiveness in pediatric patients have not been established (1).

**Related policies**

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Afrezza may be considered medically necessary in patients that are 18 years of age and older with diabetes mellitus type 1 or diabetes mellitus type 2 and if the conditions indicated below are met.

Afrezza is considered investigational in patients that are less than 18 years of age and for all other diagnosis.

**Prior-Approval Requirements**

**Age**

18 years of age or older

**Diagnoses**

Patient must have ONE the following:

1. Diabetes mellitus Type 1
   a. Inadequate response, intolerance, or contraindication to one rapid or short-acting subcutaneous insulin product
   b. Must be used in combination with long-acting (basal) insulin therapy

2. Diabetes mellitus Type 2
   a. Inadequate response, intolerance, or contraindication to one oral anti-diabetic agent
AND ALL of the following:
1. Spirometry testing before initiating, after 6 months of therapy, and annually.
2. FEV\textsuperscript{1} greater than or equal to 70 %
3. Patient has quit smoking or is in a smoking cessation program
4. **NO** history of chronic lung disease, such as asthma or COPD
5. **NOT** used for the treatment of diabetic ketoacidosis
6. No active lung cancer

**Prior – Approval ** *Renewal Requirements*

**Age**
18 years of age or older

**Diagnoses**

Patient must have **ONE** the following:

1. Diabetes mellitus Type 1  
   a. Must be used in combination with long-acting (basal) insulin therapy

2. Diabetes mellitus Type 2

**AND** the following:
1. Spirometry testing conducted annually

**Policy Guidelines**

**Pre - PA Allowance**
None

**Prior - Approval Limits**

**Duration**
6 months

**Prior – Approval ** *Renewal Limits*

**Duration**
12 months
Rationale

Summary
Afrezza is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza carries a boxed warning for risk of acute bronchospasm in patients with chronic lung disease. Prior to initiating therapy, there should be a complete medical review to identify potential lung disease. Pulmonary function tests should be administered before initiating, after 6 months of therapy, and annually, even in the absence of pulmonary symptoms. Use of Afrezza is contraindicated during hypoglycemic episodes and in patients who have had hypersensitivity reactions to Afrezza or any of its excipients. The safety and efficacy of Afrezza in pediatric patients has not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Afrezza while maintaining optimal therapeutic outcomes.

References

Policy History

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<td>December 2014</td>
<td>Addition to PA</td>
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<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update</td>
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<tr>
<td>September 2016</td>
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<tr>
<td>July 2017</td>
<td>Policy number change from 5.07.16 to 5.30.28</td>
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<td>December 2017</td>
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<td>November 2018</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.