

5.30.028

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<b>Section:</b>	Prescription Drugs	<b>Effective Date:</b>	January 1, 2023
<b>Subsection:</b>	Endocrine and Metabolic Drugs	<b>Original Policy Date:</b>	January 1, 2015
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**Last Review Date:** December 2, 2022

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## Afrezza

### Description

#### Afrezza (insulin human)

#### Background

Afrezza (insulin human) Inhalation Powder is a rapid-acting inhaled insulin indicated 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 indication: 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 (FEV<sub>1</sub>) to identify potential lung disease. Spirometry (FEV<sub>1</sub>) should also be assessed after the first 6 months of therapy, and annually thereafter, even in the absence of pulmonary

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symptoms. In patients who have a decline of  $\geq 20\%$  in FEV<sub>1</sub> 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, 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 or older with diabetes mellitus type 1 or diabetes mellitus type 2 and if the conditions indicated below are met.

Afrezza may be considered **investigational** in patients that are less than 18 years of age and for all other indication.

## Prior-Approval Requirements

**Age** 18 years of age or older

### Diagnoses

Patient must have **ONE** of 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 insulin therapy
  - c. **NOT** used in combination with an insulin pump
2. Diabetes mellitus Type 2

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- 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. FEV1 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** of the following:

1. Diabetes mellitus Type 1
  - a. Must be used in combination with long-acting insulin therapy
  - b. **NOT** used in combination with an insulin pump
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

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## 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 have 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

1. Afrezza [package insert]. Danbury, CT: MannKind Corporation; February 2020.

### Policy History

Date	Action
December 2014	Addition to PA
March 2015	Annual editorial review and reference update
September 2016	Annual editorial review and reference update Policy number change from 5.07.16 to 5.30.28
July 2017	Annual review
December 2017	Annual review and reference update
November 2018	Annual editorial review and reference update
December 2019	Annual review and reference update
March 2020	Addition of requirement that patients with Type 1 diabetes do not use in combination with an insulin pump. Also removed the word “basal” when referring to long-acting insulin
June 2020	Annual review

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March 2021	Annual editorial review and reference update
December 2021	Annual review
March 2022	Annual review
December 2022	Annual review. Changed policy number to 5.30.028

## Keywords

**This policy was approved by the FEP® Pharmacy Medical Policy Committee on December 2, 2022 and is effective on January 1, 2023.**