



Wellmark Blue Cross and Blue Shield is an Independent Licensee of the Blue Cross and Blue Shield Association.

## DRUG POLICY

# Afrezza (insulin human inhalation powder)

### NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

### BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

### DESCRIPTION

The intent of the Afrezza prior authorization program is to encourage appropriate use according to the Food and Drug Administration (FDA)-approved product labeling and/or clinical guidelines and/or clinical trials and encourage the use of cost-effective oral antidiabetic agents and/or preferred rapid acting insulin product(s) prior to the use of Afrezza.

Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with both type 1 and type 2 diabetes mellitus. Afrezza is not a substitute for long-acting insulin and must be used in combination with long-acting insulin in patients with type 1 diabetes mellitus. Afrezza is not recommended for the treatment of diabetic ketoacidosis. The safety and efficacy of Afrezza in patients who smoke has not been established and therefore is not recommended in patients who smoke or who have recently stopped smoking. Afrezza is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD), because of the risk of acute bronchospasm.

### POLICY

- I. Afrezza may be considered **medically necessary** when the following criteria are met:
  - The patient must not have any of the following: 1) Chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD) OR 2) Patient smokes or has recently stopped smoking within the past 6 months
  - The patient has been evaluated with pulmonary function tests to rule out any bronchospasms or chronic lung disease prior to initial approval and repeated with each renewal

**AND**

- The patient has been receiving a stable maintenance dose of Afrezza for at least 3 months AND
- The patient has demonstrated a reduction in hemoglobin A1c (HbA1c) since starting this therapy  
**OR**
- The requested drug is being prescribed for an adult with type 1 diabetes mellitus AND
  - The patient has experienced an intolerance or has a contraindication to the preferred injectable rapid-acting insulins  
**AND**
  - The requested drug will be used in combination with long-acting insulin  
**OR**
- The requested drug is being prescribed for an adult with type 2 diabetes mellitus AND
  - The patient has experienced an intolerance or has a contraindication to the preferred injectable rapid-acting insulins  
**AND**
  - The patient has experienced an inadequate treatment response, intolerance or has a contraindication to metformin AND another non-insulin antidiabetic agent

**Approval will be for 12 months.**

- II. Afrezza is considered **not medically necessary** for patients who do not meet the criteria set forth above.

**Note:** Injection site fatigue and safety in the workplace do not justify means for approvable as an intolerance of or contraindication to subcutaneous rapid acting insulin.

**Quantity limits apply:**

Medication	Package Description	Total units/box	Quantity Limit per 30 days
Afrezza (insulin human) inhalation	4/8 unit combo (90x4 & 90x8)	1080 units/box	3 boxes (3240 units)/30 days
	8/12 unit combo (90X8 & 90X12)	1800 units/box	2 boxes (3600 units)/30 days
	8/12 unit combo (90X8 & 90X12)	1800 units/box	2 boxes (3600 units)/30 days
	90 cartridges (4 unit)	360 units/box	6 boxes (2160 units)/30 days
	90 cartridges (8 unit)	720 units/box	5 boxes (3600 units)/30 days
	90 cartridges (12 unit)	1080 units/box	3 boxes (3240 units)/30 days

**PROCEDURES AND BILLING CODES**

**To report provider services, use appropriate CPT\* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.**

- Code(s), if applicable.

**REFERENCES**

- Afrezza® [prescribing information]. MannKind Corporation. Danbury, CT. March 2021.
- American Diabetes Association. Standards of Medical Care in Diabetes – 2026: Diabetes Care January 2026; 49(Supplement 1). S1-S371
- Blonde L, Umpierrez GE, Reddy SS, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: Developing a Diabetes Mellitus Comprehensive Care Plan-2022 Update. Endocr Pract. 2022;28(10):923-1049.

- Davies MJ, Aroda VR, Collins BS, et. al. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). Diabetes Care. 2022;45(11):2753-2786.\_

## **POLICY HISTORY**

**Policy #:** 05.01.83

**Policy Creation:** September 2015

**Reviewed:** January 2026

**Revised:** January 2025

**Current Effective Date:** March 14, 2025