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## 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
- AND**
- The patient has been receiving Afrezza for at least 3 months **AND** has demonstrated an expected reduction in HbA1c since starting this therapy; **OR**
  - The patient has been evaluated with pulmonary function tests to rule out any bronchospasms or chronic lung disease

**AND**

- The patient has experienced an FDA-labeled contraindication or intolerance to the preferred injectable rapid-acting insulin, Novolog, which is not expected to occur with Afrezza; **OR**
- The patient is physically impaired and unable to administer injectable insulin

**AND**

- Afrezza is being prescribed for type 1 diabetes mellitus in an adult patient **AND** Afrezza will be used in combination with a long-acting insulin; **OR**
- Afrezza is being prescribed for type 2 diabetes mellitus in an adult patient **AND** the patient has experienced an inadequate treatment response, contraindication or intolerance to both metformin **AND** another oral antidiabetic agent (i.e. sulfonylurea, thiazolidinedione, or a dipeptidyl peptidase-4 inhibitor) when used in combination

**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 (60x4 & 30x8)	480 units/box	5 boxes (2400 units)/30 days
	4/8 unit combo (30x4 & 60x8)	600 units/box	6 boxes (3600 units)/30 days
	4/8 unit combo (90x4 & 90x8)	1080 units/box	3 boxes (3240 units)/30 days
	8/12 unit combo (60X8 & 30X12)	840 units/box	4 boxes (3360 units)/30 days
	8/12 unit combo (90X8 & 90X12)	1800 units/box	2 boxes (3600 units)/30 days
	4/8/12 unit combo (60X4,60X8, & 60X12)	1440 units/box	2 boxes (2880 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.

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## POLICY HISTORY

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