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
- The patient has been evaluated with pulmonary function tests to rule out any bronchospasms or chronic lung disease

AND
- The patient has been receiving Afrezza for at least 3 months AND

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- 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 insulin, Novolog, which is not expected to occur with Afrezza **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 insulin, Novolog, which is not expected to occur with Afrezza **AND**
  - The patient has experienced an inadequate treatment response, intolerance or has a contraindication 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 (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-2021: Diabetes Care January 2021;44(Supplement1). S1-S226.
- Garber AJ, Abrahamson MJ, Barzilay JI, et al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm-2020 Executive Summary, Endocr Pract. 2020; 26 (No 1);107-139.

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POLICY HISTORY

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