

Pharmacy Policy Bulletin

Title: Insulin human, inhalation (Afrezza®)

Policy #: Rx.01.169

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for insulin human, inhalation (Afrezza®) as provided under the member's prescription drug benefit.

Description:

Insulin stimulates peripheral glucose uptake by inhibiting hepatic glucose production and glucose uptake by skeletal muscle and fat.

Afrezza® is a rapid-acting insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

Policy:

INITIAL CRITERIA: Afrezza® is approved when ALL of the following are met:

- A. Member is 18 years of age or older; and
- B. One of the following:
 1. Both of the following:
 - a. Diagnosis of type I diabetes mellitus; and
 - b. Used in combination with a long-acting insulin (e.g., Lantus)
 2. Diagnosis of type II diabetes mellitus; and
- C. Spirometry (FEV₁) completed prior to initiation of therapy to identify potential lung disease (must provide the result); and
- D. Member is a non-smoker for a minimum of 6 months; and
- E. Absence of chronic lung disease such as asthma or chronic obstructive pulmonary disease; and
- F. Prescribed by or in consultation with an endocrinologist

Initial authorization duration: 6 months

REAUTHORIZATION CRITERIA: Afrezza® is re-approved when the following are met:

- A. There is documentation of spirometry value (FEV₁) has not declined \geq 20% from baseline; and
- B. There is documentation of positive clinical response to therapy

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

Acute bronchospasm has been observed in patients with asthma and COPD using Afrezza®.

Afrezza® is contraindicated in patients with chronic lung disease such as asthma or COPD.

Before initiating Afrezza®, perform a detailed medical history, physical examination, and spirometry (FEV₁) to identify potential lung disease in all patients.

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Afrezza® (insulin human, inhalation) [package insert]. Bridgewater, NJ: Sanofi-aventis US LLC. March 2021. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=29f4637b-e204-425b-b89c-7238008d8c10&type=display>. Accessed October 05, 2022.

Insulin human inhalation. Micromedex. Available from: <http://www.micromedexsolutions.com>. Accessed October 05, 2022.

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Afrezza®	Insulin human, inhalation

Cross References:

Off-Label Use Rx.01.33

Policy Version Number:	9.00
P&T Approval Date:	September 15, 2022
Policy Effective Date:	January 01, 2023
Next Required Review Date:	September 15, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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