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:

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

1. Use in the age group supported by FDA labeling; and
2. Diagnosis of diabetes mellitus; and
3. Spirometry (FEV_1) completed prior to initiation of therapy to identify potential lung disease (must provide the result); and
4. Member is a non-smoker for a minimum of 6 months; and
5. Absence of chronic lung disease such as asthma or chronic obstructive pulmonary disease; and
6. Absence of active lung cancer or history of lung cancer

Initial authorization duration: 6 months

Re-authorization criteria

Afrezza® is re-approved when there is documentation of spirometry value (FEV_1) has not declined ≥ 20% from baseline

Re-authorization duration: indefinite

Black Box Warning:

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 (FEV_1) 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. October 2018. Available at: https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=29f4637b-e204-425b-b89c-7238008d8c10&type=display. Accessed November 26, 2018.

Insulin human inhalation. Micromedex. Available from: http://www.micromedexsolutions.com. Accessed November 26, 2018.

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:

N/A

Policy Version Number:	5.00
P&T Approval Date:	October 11, 2018
Policy Effective Date:	January 1, 2019
Next Required Review Date:	October 11, 2019