SECURING ACCESS TO AFREZZA® FOR YOUR PATIENTS

afrezza® (insulin human) Inhalation Powder

Some insurance plans may require a **Prior Authorization (PA)** before approving the use of Afrezza.

4 IN 5

patients will obtain coverage for Afrezza® however; some plans may require extra documentation before approving Afrezza.[1]

The majority of payers who require a PA for Afrezza want to see that patients have tried the preferred injectable rapid-acting insulin first.

90%

of Afrezza electronic Prior Authorizations (ePAs) will receive a response from the payer within 24 hours after submission.[1]

To streamline the approval process, it is strongly encouraged that you submit PAs for Afrezza electronically.

Although coverage criteria for Afrezza may vary, the PA process is generally predictable across plans. To simplify the PA process, we have identified some helpful practices for healthcare providers.

The majority of Afrezza PAs will require the following information:

- Diagnosis of type 1 or type 2 diabetes
- Patient is 18 years or older
- Lung Function Test (FEV_1) baseline value and date of test
- No history of chronic lung disease, such as COPD or asthma
- Patient is a non-smoker or has quit in the last 6 months

DOCUMENTATION FOR INSULIN EXPERIENCED PATIENTS

- Patient with type 1 diabetes is also on long-acting insulin
- Patient has tried another injectable rapid-acting insulin and experienced inadequate clinical results, such as:
  - No improvements in glycemic control
  - Increased side effects, such as hypoglycemia
  - Allergic reactions, such as injection site irritation
  - Lipohypertrophy

DOCUMENTATION FOR INSULIN NAIVE PATIENTS

- Patient has tried at least two oral glucose lowering agents
- Rationale for why the patient can't take the preferred rapid-acting injectable insulin, such as:
  - Fear of injections
  - Inability to self-administer injectable insulin, such as physical, mental, or visual impairment

IMPORTANT SAFETY 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.**

Indications and Usage

- Afrezza (insulin human) Inhalation Powder is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

Limitations of Use

- In patients with type 1 diabetes, must use with a long-acting insulin
- Not recommended for the treatment of diabetic ketoacidosis
- Not recommended in patients who smoke

Contraindications

- During episodes of hypoglycemia
- Chronic lung disease, such as asthma, or chronic obstructive pulmonary disease
- Hypersensitivity to regular human insulin or any of the AFREZZA excipients

OVERCOMING PAYER DENIALS FOR AFREZZA®

afrezza® (insulin human) Inhalation Powder

When submitting an appeal to a payer, it helps to clearly and concisely describe the intended therapeutic outcome and potential consequences if the intervention is denied.

Although there is not a standardized process that applies across all payers when appealing a denial for Afrezza®, the goal is the same: **clinical justification of a patient's need and appropriateness for the therapy.**

Patient History

- **DISEASE AND TREATMENT HISTORY**
  Including failure with, or lack of response to, the preferred covered products. For example: no improvements in glycemic control, A1C, or time-in-range, increased side effects (such as hypoglycemia), and or allergic reactions (such as injection-site irritation).
- **PATIENT INABILITY TO TAKE OR USE THE PREFERRED INJECTABLE RAPID-ACTING INSULIN**
  For example: fear of injections, physical inability to self-administer, lipohypertrophy, and or visual impairment.
- **HISTORY OF POSITIVE RESPONSES TO AFREZZA AND POTENTIAL CONSEQUENCES OF SWITCHING**
  For example: increased patient compliance, improvements in glycemic control, reduction in A1C, increased time-in-range, and decreased side effects, such as reduced rates of hypoglycemia.

Clinical Benefits Unique to Afrezza

- Afrezza significantly lowers glucose concentrations post-meal and significantly reduces PPG excursions (PPGE).[2]
- Afrezza significantly reduces postprandial hypoglycemic events compared with subcutaneous (SC) rapid-acting insulin.[3]
- Switching to Afrezza can deliver significantly more time-in-range.[2]
- Afrezza is the only ultra rapid-acting insulin and the only therapeutic option that provides a needle-free delivery.[4]
- For patients with type 2 diabetes, Afrezza has demonstrated superior A1C reduction compared to OAs alone.[4]
- Afrezza provides mealtime flexibility, allowing patients to inhale when food arrives, and, if needed, to take additional doses at 1 and 2 hours post-meal.[2,4]

WE ARE HERE TO HELP

AfrezzaAssist℠ is a one-stop-hub solution that helps your patients get access to Afrezza and stay on therapy. Services include comprehensive reimbursement support and pharmacy fulfillment, as well as product training and support to help improve patient care.

TELEPHONE (TOLL-FREE)
1-844-323-7399

HOURS
Monday – Friday 8:00am – 8:00pm ET

References: 1. Data on file. MannKind Corporation. 2.Akturk GK, Snell-Bergeon JK, Rewers A, et al. Improved postprandial glucose with inhaled Technosphere insulin compared with insulin aspart in patients with type 1 diabetes on multiple daily injections: the STAT study. Diabetes Technol Ther. 2018;20(10):639-647. 3. Seaquist ER, Blonde L, McGill JB, et al. Hypoglycaemia is reduced with use of inhaled Technosphere® Insulin relative to insulin aspart in type 1 diabetes mellitus. Diabet Med. 2020;37(5):752-759. 4. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation.

IMPORTANT SAFETY INFORMATION (cont.)

Warnings and Precautions
AFREZZA may cause serious side effects that can lead to death, including **Acute Bronchospasm, Hypoglycemia, Decline in Pulmonary Function, Lung Cancer, Diabetic Ketoacidosis, Hypersensitivity Reactions, Hypokalemia, and Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs).**

Full Prescribing Information, including **BOXED WARNING**, is available on www.afrezzahcp.com.