

Afrezza Assist®  
supported by aspn Pharmacies

and Patient Trainers



## Access and support made easier for you and your patients

The 3-step process for starting AFREZZA®

STEP 1: Prescribe

STEP 2: Coverage

STEP 3: Train & Educate

### Indications and Usage:

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

**Limitations of Use:** Not recommended for the treatment of diabetic ketoacidosis, not recommended in patients who smoke or have recently stopped smoking.

### Important Safety Information

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

- Acute bronchospasm has been observed in AFREZZA-treated patients with asthma and COPD.
- 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<sub>1</sub>) to identify potential lung disease in all patients.

### Contraindications

AFREZZA is contraindicated: during episodes of hypoglycemia, in patients with chronic lung disease (such as asthma or chronic obstructive pulmonary disease [COPD]) because of the risk of acute bronchospasm, and in patients with hypersensitivity to regular human insulin or any of the excipients in AFREZZA.

For Important Safety Information, see pages 10-11.  
Full Prescribing Information, including **BOXED WARNING**,  
is available on [Afrezzahcp.com](http://Afrezzahcp.com), or from your  
MannKind representative.

 **afrezza**  
(insulin human) Inhalation Powder



STEP  
1



## Prescribe

# The right dose for maximum clinical benefits

## Dosing for mealtime

- In clinical trials, by the end of the study, the range of average dose per meal was 12-16 AFREZZA® units<sup>1</sup>
- For insulin-naïve individuals, start on 4 units of AFREZZA at each meal<sup>2</sup>

Scan for help with converting from  
injectable insulin units to AFREZZA

or visit <https://afrezzahcp.com/dosing/>



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## Prescription dosing guide

- It may take 1.5-2x of AFREZZA units to achieve a comparable effect to SC RAI<sup>3,4</sup>

### Insulin dose conversion & anticipated dose after titration<sup>2,4</sup>

Injected mealtime insulin units	Starting AFREZZA units	Anticipated AFREZZA units after titration*
Up to 4	4	4-8
5-8	8	8-12
9-12	12	12-20
13-16	16	16-24
17-20	20	20-32
21-24	24	24-36

\*Calculation based on the 1.5-times conversion rate from injectable insulin units.

### Mealtime correction doses at 1 and/or 2 hours postmeal<sup>4</sup>

Blood glucose	1 hour	2 hours
≤150 mg/dL	-	-
151-200 mg/dL	4 units	-
≥201 mg/dL	8 units	4 units <sup>†</sup>

<sup>†</sup>2-hour correction used only if BG is ≥201 mg/dL and has not decreased by ≥50 mg/dL between 1 and 2 hours.

Data from the STAT study of patients with T1D with A1C levels 6.5% to 10%. Individuals were randomized to treatment with titrated AFREZZA (n=22) or titrated SC RAI aspart (n=34) and included in the final analysis. All were required to wear a real-time CGM throughout the trial. Patients in the AFREZZA group were advised to take supplemental inhalations at 1 and 2 hours after meals if indicated based on PPG values.<sup>4</sup>

A1C=glycated hemoglobin; BG=blood glucose; CGM=continuous glucose monitor; RAI=rapid-acting insulin; SC=subcutaneous; T1D=type 1 diabetes.

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# Streamline patient coverage through 3 easy steps




## **A** Write an AFREZZA<sup>®</sup> prescription

e-prescribe through your EMR (electronic prescription) or write an AFREZZA prescription (Prescription Intake Form)

Prescription must include quantity, directions for use (total daily dose), days' supply (ie, 30 days), and # of refills

The NDC number ensures prescribing the correct product in EMR

### Important prescription information to include

Units per meal	How to write	NDC # and contents of 1 box*
<b>4-16</b>	<ul style="list-style-type: none"> <li>Inhale 4-16 units by mouth at mealtime and additional units as needed for glucose control</li> <li><b>Max total daily dose:</b> 48 units=1 box; 96 units=2 boxes (360 cartridges); 144 units=3 boxes (540 cartridges)</li> <li>30-day supply</li> <li><b>Refills:</b> 12</li> </ul>	<p><b>NDC 47918-0902- 18</b></p>  <p>[60] 4-Unit Cartridges [60] 8-Unit Cartridges [60] 12-Unit Cartridges Total: 180 cartridges</p>
<b>4-12</b>	<ul style="list-style-type: none"> <li>Inhale 4-12 units by mouth at mealtime and additional units as needed for glucose control</li> <li><b>Max total daily dose:</b> 36 units=1 box; 72 units=2 boxes (360 cartridges); 108 units=3 boxes (540 cartridges)</li> <li>30-day supply</li> <li><b>Refills:</b> 12</li> </ul>	<p><b>NDC 47918-0880- 18</b></p>  <p>[90] 4-Unit Cartridges [90] 8-Unit Cartridges Total: 180 cartridges</p>
<b>8-20</b>	<ul style="list-style-type: none"> <li>Inhale 8-20 units by mouth at mealtime and additional units as needed for glucose control</li> <li><b>Max daily dose:</b> 60 units=1 box; 120 units=2 boxes (360 cartridges); 180 units=3 boxes (540 cartridges)</li> <li>30-day supply</li> <li><b>Refills:</b> 12</li> </ul>	<p><b>NDC 47918-0898- 18</b></p>  <p>[90] 8-Unit Cartridges [90] 12-Unit Cartridges Total: 180 cartridges</p>

\*Examples shown are the most commonly prescribed boxes. Prescribe additional boxes as needed to control glucose levels. AFREZZA should be dosed based on the patient's metabolic needs. Go to <https://afrezzahcp.com/dosing/> for more information.

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**B Submit the AFREZZA prescription to:**

ASPEN Pharmacies. ASPEN Pharmacies will determine cost and coverage and coordinate fulfillment for the patient.

ASPEN Pharmacies  
 290 W. Mount Pleasant Ave.  
 Livingston, NJ 07039  
**NPI: 1538590690 | NCPDP: 3147863**  
**Phone: 844-323-7399**  
**Fax: 800-561-6174**  
**Hours: 8:30AM - 8:00PM EST**

**Monitoring lung function (FEV<sub>1</sub>) is recommended with AFREZZA and may be required for prior authorization**

**C Complete the Afrezza Questionnaire and fax to 800-561-6174**

SECTION 2 - AFREZZA QUESTIONNAIRE  
(Note: information provided below will be used to complete prior authorization request)

PRESCRIBER INFORMATION			
First Name:	Last Name:	NPI:	
Address:	City:	State:	Zip:
HCP Contact:	Phone:	Fax:	Email:
PATIENT INFORMATION			
First Name:	Last Name:	DOB:	
Address:	City:	State:	Zip:
CLINICAL INFORMATION			
What is the patient's diagnosis? <input type="checkbox"/> Type 1 Diabetes <input type="checkbox"/> Type 2 Diabetes <input type="checkbox"/> Other: _____			
Check ALL medications that the patient has tried and failed. (include any medications not listed in the "Other" checkbox): <input type="checkbox"/> Novolog <input type="checkbox"/> Humalog <input type="checkbox"/> Novolin <input type="checkbox"/> Humulin <input type="checkbox"/> Humalog <input type="checkbox"/> J200 <input type="checkbox"/> J500 <input type="checkbox"/> Fiasp <input type="checkbox"/> Humalog <input type="checkbox"/> Novolin <input type="checkbox"/> Humulin <input type="checkbox"/> Humalog <input type="checkbox"/> J200 <input type="checkbox"/> J500 <input type="checkbox"/> Other: _____ (Specify in Note Section below)			
Reasons for medication treatment failures that were checked above: (Check all below that apply) <input type="checkbox"/> Patient not achieving A1C Goal <input type="checkbox"/> Blood Glucose Variability (Lack of Time in Range) <input type="checkbox"/> Intolerance to Therapy or Hypersensitivity <input type="checkbox"/> Experienced Adverse Event including increased Hypoglycemia <input type="checkbox"/> Contraindication <input type="checkbox"/> Other (Please reference chart notes): _____			
In the prescriber's opinion, alternatives will not be as effective for the patient due to: (Check all below that apply) <input type="checkbox"/> Lipohypertrophy with malabsorption <input type="checkbox"/> Gastroparesis <input type="checkbox"/> High risk of Hypoglycemia <input type="checkbox"/> Needle Phobia and unable to self-inject to the degree that patient presents with uncontrolled diabetes due to: <input type="checkbox"/> Physical Disability <input type="checkbox"/> Mental Disability <input type="checkbox"/> Visual Impairment			
Check ALL the following that apply: <input type="checkbox"/> Contraindications to Afrezza have been ruled out <input type="checkbox"/> FEV1 spirometry testing has been completed prior to initiation of therapy <input type="checkbox"/> Type 1 diabetes patient will also receive basal insulin via injection or pump <input type="checkbox"/> Diabetes controlled on Afrezza medication and with no adverse effects			
Note Section:  _____ _____			
All information is true and accurate to the best of my knowledge. Please sign below to validate. Prescriber Signature: _____ Date: _____			

**If a PA is required, ASPEN Pharmacies will provide an AFREZZA Questionnaire via fax or within the ASPEN Provider Portal. Complete the form and attach patient demographics/face sheet and patient chart notes.**

For Important Safety Information, see pages 10-11. Full Prescribing Information, including **BOXED WARNING**, is available on [Afrezzahcp.com](http://Afrezzahcp.com), or from your MannKind representative.



## Enhance patient compliance and make care more accessible through



Our goal is to put patients first by minimizing cost barriers through financial support programs. MannKind offers several options to help with the cost of AFREZZA®, depending on the type of insurance coverage your patients have.

Commercial insurance	Medicare Part D	Cash option
<p><b>Pay as little as \$35 per month</b></p> <ul style="list-style-type: none"> <li>• Subject to eligibility criteria and maximum benefit limitations</li> <li>• Additional cost savings (reduced copay) may be possible when combined with insurance coverage</li> <li>• See <a href="http://AFREZZAsavingscard.com">AFREZZAsavingscard.com</a> for complete program terms and conditions</li> </ul>	<p><b>Pay as little as \$35 per month</b></p> <ul style="list-style-type: none"> <li>• Assistance is available for eligible patients</li> <li>• See <a href="http://medicare.gov/coverage/insulin">medicare.gov/coverage/insulin</a> for complete program terms and conditions</li> </ul>	<p><b>Pay as little as \$3 per day for a 30-day supply<sup>1</sup></b></p> <ul style="list-style-type: none"> <li>• Prescription must be submitted to ASPN Pharmacies to access this cash pay option</li> </ul>

- ASPN Pharmacies will determine cost and coverage for your patients and coordinate fulfillment from ASPN Pharmacy or through a local pharmacy (if requested).

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STEP  
2



## Navigate the coverage and authorization process through



Phone  
844-4MANKND  
(844-462-6563)

Fax  
800-561-6174

Hours  
Monday – Friday, 8:30 AM - 8:00 PM ET

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STEP  
**3**

## Train & Educate

Proper training and education is critical for your patients who are new to AFREZZA®, or for current users who may need a refresher training. MannKind offers in-person or virtual training (based on availability) for all patients.

For Important Safety Information, see pages 10-11. Full Prescribing Information, including **BOXED WARNING**, is available on [Afrezzahcp.com](https://www.afrezzahcp.com), or from your MannKind representative.

 **afrezza.**  
*(insulin human) Inhalation Powder*



## Empowering your patients at every step of their journey

**Our team of experienced, credentialed, certified Patient Trainers and dedicated Support Team are here to help guide your patients**

With our guided training, your patients will successfully learn how to **correctly use** and **safely store** their prescribed treatment.

- To get started, complete a [Digital Start Sheet here](#) or fax or email a completed Start Sheet to our Training Support team  
**Fax:** 866-284-6950 | **Email:** [afrezzatraining@mannkindcorp.com](mailto:afrezzatraining@mannkindcorp.com)
  - Start Sheets are available from your MannKind Sales Representative or by calling our HCP Resource Support Team at 844-4MANKND
- We will contact your patient to schedule their training session
- A certified trainer will meet with your patient and begin the training
- **Support from our team is ongoing.** Patients can also call our **Training Support Hotline at 877-523-1199** to speak with a certified trainer

For further support and to request additional patient resources, please call your **MannKind Sales Representative** or our **HCP Resources Support Team: 844-4MANKND (844-462-6563)**

**References:** 1. Data on file (Range of average dose (of TI) per meal). MannKind Corporation. 2. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation. 3. Bode BW, McGill JB, Lorber DL, Gross JL, Chang PC, Bregman DB. Inhaled Technosphere insulin compared with injected prandial insulin in type 1 diabetes: a randomized 24-week trial. *Diabetes Care*. 2015;38(12):2266-2273. 4. Akturk HK, 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.

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# Important Safety Information

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**Limitations of Use:** Not recommended for the treatment of diabetic ketoacidosis, not recommended in patients who smoke or have recently stopped smoking.

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

- **Acute bronchospasm has been observed in AFREZZA-treated patients with asthma and COPD.**
- **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<sub>1</sub>) to identify potential lung disease in all patients.**

## Contraindications

AFREZZA is contraindicated: during episodes of hypoglycemia, in patients with chronic lung disease (such as asthma or chronic obstructive pulmonary disease [COPD]) because of the risk of acute bronchospasm, and in patients with hypersensitivity to regular human insulin or any of the excipients in AFREZZA.

## Warnings and Precautions

**Acute Bronchospasm:** In a study of patients with asthma whose bronchodilators were temporarily withheld for assessment, bronchoconstriction and wheezing following AFREZZA dosing was reported. Before initiating therapy, evaluate all patients with a medical history, physical examination, and spirometry (FEV<sub>1</sub>) to identify potential underlying lung disease. Do not use in patients with chronic lung disease such as asthma or COPD.

**Hypoglycemia or Hyperglycemia with Changes in Insulin Regimen:** Glucose monitoring is essential for patients receiving insulin therapy. Changes in insulin strength, manufacturer, type, or method of administration may affect glycemic control and predispose to hypoglycemia or hyperglycemia. These changes should be made under close medical supervision and the frequency of blood glucose monitoring should be increased. For patients with type 2 diabetes, dosage modifications of concomitant oral antidiabetic treatment may be needed.

**Hypoglycemia:** Hypoglycemia is the most common adverse reaction associated with insulins, including AFREZZA. Severe hypoglycemia can cause seizures, may be life-threatening, or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place an individual and others at risk in situations where these abilities are important (e.g., driving or operating other machinery). Hypoglycemia can happen suddenly, and symptoms may differ across patients and change over time in the same patient. Patients and caregivers should be educated to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia.

Full Prescribing Information, including **BOXED WARNING**, is available on [Afrezzahcp.com](http://Afrezzahcp.com), or from your MannKind representative.

# Important Safety Information cont'd

**Decline in Pulmonary Function:** AFREZZA causes a decline in lung pulmonary function over time as measured by FEV<sub>1</sub>. In clinical trials excluding patients with chronic lung disease and lasting up to 2 years, AFREZZA-treated patients experienced a small (40 mL) but greater FEV<sub>1</sub> decline than comparator-treated patients. Assess pulmonary function with spirometry at baseline, after the first 6 months of therapy and annually thereafter even in the absence of pulmonary symptoms. In patients who have a decline of  $\geq 20\%$  in FEV<sub>1</sub> from baseline, consider discontinuing AFREZZA. Consider more frequent lung function assessment in patients with pulmonary symptoms, e.g., wheezing, bronchospasm, breathing difficulties, or persistent or recurring cough. If symptoms persist, discontinue AFREZZA.

**Lung Cancer:** In clinical trials, 2 cases of lung cancer were observed in patients exposed to AFREZZA while no cases were reported for the comparators. In both cases, a prior history of heavy tobacco use was identified as a risk factor for lung cancer. Two additional cases of lung cancer (squamous cell and lung blastoma) were reported in non-smokers exposed to AFREZZA after the trial completion. These data are insufficient to determine whether AFREZZA has an effect on lung or respiratory tract tumors. In patients with active lung cancer, a prior history of lung cancer, or in patients at risk of lung cancer, consider whether the benefits of AFREZZA use outweigh this potential risk.

**Diabetic Ketoacidosis (DKA):** In clinical trials enrolling patients with type 1 diabetes, diabetic ketoacidosis (DKA) was more common in AFREZZA-treated patients (0.43%; n=13) than in comparator-treated patients (0.14%; n=3). Patients with type 1 diabetes should always use AFREZZA in combination with basal insulin. In patients at risk for DKA, such as those with an acute illness or infection, increase the frequency of glucose monitoring and consider discontinuing AFREZZA and giving insulin using an alternate route of administration.

**Hypersensitivity Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including AFREZZA. If hypersensitivity reactions occur, discontinue AFREZZA, treat per standard of care and monitor until symptoms and signs resolve.

**Hypokalemia:** All insulin products, including AFREZZA, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Closely monitor potassium levels in patients at risk of hypokalemia and treat if indicated.

**Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs):** Fluid retention, which may lead to or exacerbate heart failure, can occur with concomitant use of TZDs and insulin. Observe these patients for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the TZD should be considered.

## Drug Interactions

Certain drugs may affect glucose metabolism, increasing the risk of hypoglycemia, or decreasing or increasing the blood glucose lowering effect of AFREZZA. Dose adjustment and increased frequency of blood glucose monitoring may be required. Co-administration of beta-blockers, clonidine, guanethidine, and reserpine with AFREZZA may reduce the signs and symptoms of hypoglycemia. For full list, see Prescribing Information.

## Adverse Reactions

The most common adverse reactions associated with AFREZZA are hypoglycemia, cough, and throat pain or irritation.

To report SUSPECTED ADVERSE REACTIONS, contact MannKind Corporation at 1-877-323-8505 or FDA at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 (1-800-332-1088).

Full Prescribing Information, including **BOXED WARNING**, is available on [Afrezzahcp.com](http://Afrezzahcp.com), or from your MannKind representative.



# Patient access to AFREZZA begins with you

STEP

1

Prescribe

Prescribing the right dose of AFREZZA® for maximum clinical benefits

STEP

2

Coverage

### Coverage in 3 easy steps:

- Write the AFREZZA prescription
- Submit the prescription
- Complete the PA

STEP

3

Train & Educate

- Schedule a certified AFREZZA trainer for patient training support and fax start sheet
- Request additional patient resources

## Important AFREZZA Support Services contact information

mannkind **Cares**<sup>®</sup>  
*Offers*

### Patient Trainers

Patient Training & Support Hotline

Phone (direct line) **877-523-1199**

Hours **Monday – Friday, 8:30 AM - 6:30 PM ET**

**AfrezzaAssist**<sup>®</sup>  
supported by **ASPN** Pharmacies

Phone

**844-4MANKND**  
(844-462-6563)

Fax

**800-561-6174**

Hours **Monday – Friday, 8:30am - 8:00pm ET**

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**mannkind**

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(insulin human) Inhalation Powder