



WELCOME TO AFREZZA[®]

A Guide for Healthcare Professionals & Office Staff

Please see [Important Safety Information](#), including **BOXED WARNING**, for AFREZZA on [page 2](#) of this piece. Click to view the [Full Prescribing Information](#) for AFREZZA.

IMPORTANT SAFETY INFORMATION

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.

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 (FEV₁) 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 (FEV₁) 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.

Decline in Pulmonary Function: AFREZZA causes a decline in lung pulmonary function over time as measured by FEV₁. 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 FEV₁ 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 ≥20% in FEV₁ 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 or call 1-800-FDA-1088 (1-800-332-1088).

Please see [Full Prescribing Information](#) for AFREZZA.



GETTING STARTED WITH AFREZZA®

Once you have a patient that is ready to start their Afrezza journey, this guide will help you understand MannKind's support solutions to keep the process simple and easy for both the office and the patient.

EXPLORE WHAT THIS GUIDE HAS TO OFFER:

Conduct a Patient Breathing Test	4
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Afrezza is a rapid-acting inhaled human insulin indicated to improve glycemic control in adult patients with diabetes mellitus.¹



References:

1. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation.

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THE FIRST STEP TO GETTING A PATIENT STARTED ON AFREZZA: CONDUCT A PATIENT BREATHING TEST.

The FEV₁ test is one of the tools that can be used to establish a baseline assessment before initiating Afrezza, as well as monitor lung function after 6 months of therapy and annually thereafter.¹



FOR YOUR OFFICE

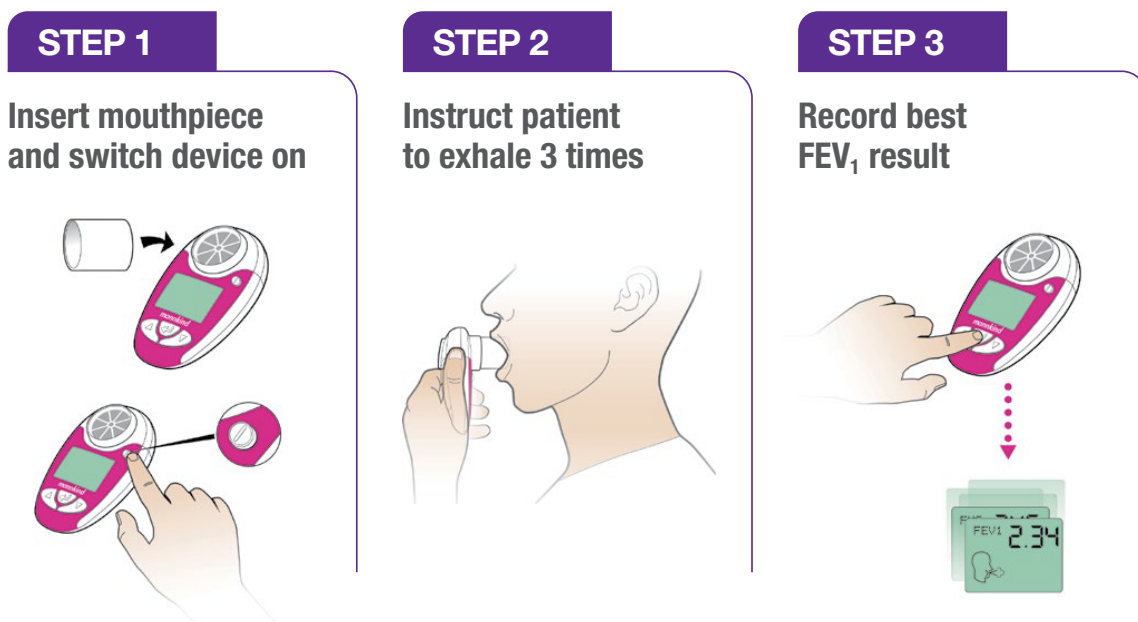
For healthcare professionals, MannKind will ship one complimentary FEV₁ device and 10 disposable mouthpieces directly to your office. Contact your Territory Business Manager, or visit afrezzahcp.com/request-a-rep.



DIRECT TO PATIENTS

For patients with diabetes, MannKind will ship one complimentary FEV₁ device and instructions directly to their residence for convenient at-home testing. Doctors requesting FEV₁s for their patients should complete the Patient Consent Form at <https://afrezza.com/fev1/>.

Conducting a FEV₁ test



Tips for your patients to conduct an FEV₁ test

- Sit upright for testing²
- Holding the head high, breathe in as deeply as possible²
- Holding the breath, place mouthpiece into the mouth, biting lightly and with lips firmly sealed around it²
- Blow out as HARD and as FAST as possible for one second or more, ensuring not to block the mouthpiece with the tongue or teeth²

References:

1. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation.
2. ASMA-1 Asthma Monitor." Vitalograph, vitalograph.com/intl/product/asma-1-asthma-monitor/. Accessed 14 June 2023

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DOSING INSTRUCTIONS

Clinical studies have suggested that it may take ~1.5- 2x the amount of Afrezza to achieve a comparable glucose-lowering effect to injected insulin.^{1,2}

The chart below is a starting point to help you and your patients convert their current mealtime insulin dose to Afrezza. For insulin naive individuals, start on 4 units of Afrezza at each meal.³

INSULIN DOSE CONVERSION TABLE AND ANTICIPATED DOSE AFTER TITRATION^{1,3}

Injected Mealtime Insulin (units)	Starting Afrezza Dose (units)	Anticipated Afrezza Dose (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.



Please scan or visit www.afrezzahcp.com/dosing or www.afrezzahcp.com/dosing-calculator to calculate the most appropriate Afrezza starting dose.

The following guide will help create a step-by-step individualized plan for your patients.

Step 1 Take Prescribed Afrezza Dose

BREAKFAST	LUNCH	DINNER	SNACK
units	units	units	units

Step 2 Check Blood Glucose

hour(s) after the start of the meal, check your blood glucose* to see how Afrezza is working for you

Target After-Meal Blood Glucose _____ to _____ mg/dL

*American Diabetes Association suggests 1–2 hours after the start of the meal.⁴

Step 3 Give a Correction Dose, if Needed

AFTER-MEAL BLOOD GLUCOSE	CORRECTION DOSE
Blood glucose greater than: _____ mg/dL	Take _____ units
Blood glucose greater than: _____ mg/dL	Take _____ units

Step 4 Adjust Dose, if Needed

- If you require treatment for low blood glucose OR correction doses for high blood glucose for or more days, consult your HCP to consider adjusting your prescribed Afrezza dose
- Continue adjusting dose until your after-meal blood glucose is consistently within your target

This dosing worksheet is available as a tear sheet you can request from your Territory Business Manager, or you can download it on our website at afrezzahcp.com/resources.

References:

1. 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. 2. Grant M, Heise T, Baughman R. Comparison of pharmacokinetics and pharmacodynamics of inhaled Technosphere Insulin and subcutaneous insulin lispro in the treatment of type 1 diabetes mellitus. *Clin Pharmacokinet*. 2022;61(3):413-422. 3. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation. 4. ElSayed NA, Aleppo G, Aroda VR et al. on behalf of the American Diabetes Association, 6. Glycemic Targets: *Standards of Care in Diabetes—2023*. *Diabetes Care* 1 January 2023; 46 (Supplement_1): S97–S110.

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WRITING THE PRESCRIPTION

3 steps:

1. Write the Prescription

Prescription must include NDC, Quantity, Directions for use (Total Daily Dose), Day supply (i.e. 30 days), and # of refills.

2. Submit the Prescription

Submit the Prescription to UBC Pharmacy, LLC. AfrezzaAssist® will determine cost and coverage to coordinate fulfillment.

3. Complete the Prior Authorization

If a PA is required, your office will receive a questionnaire form via fax from CloudTop. Please complete the form and attach chart notes (if applicable). If denied, you will receive follow up and instructions.

Rx Example Afrezza Prescription:

Drug:

Afrezza Inhalation Powder, 4u/8u (#180 ct)

Total Quantity:

#180 cartridges (30 day supply)

NDC:

NDC 47918-0880-18

Directions:

Inhale 4-12 units by mouth with meals 3 times a day.
Titrate as directed.

Maximum daily dosage: 36 units.

Refills: **12**

Not an actual prescription

To ensure your patients can access these options,
please submit prescriptions to AfrezzaAssist®

Submit the Rx to UBC Pharmacy, the AfrezzaAssist® Intake Pharmacy

UBC Pharmacy LLC, 600 Emerson Road Suite 300 Creve Coeur, MO 63141

NPI: 1962978858

FAX: 866-750-9260 Phone: 855-822- 7948

AfrezzaAssist® will determine cost and coverage for your patients and coordinate fulfillment within the Afrezza Specialty Pharmacy Network or through a local pharmacy (if requested).*

*Prescription must be submitted to AfrezzaAssist (UBC Pharmacy) to access Direct Purchase Program option.



WEBSITE

<https://afrezzahcp.com/afrezzaassist>



TELEPHONE (TOLL-FREE)

1-84 4-3 23-7399

1-84 4-3- AFREZZA

HOURS

Monday - Friday 8am - 8pm ET

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SIMPLIFYING THE PA PROCESS

To simplify the PA process, we have identified some helpful practices for healthcare providers and their office staff.

WHAT NEEDS TO BE INCLUDED?

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 (FEV₁) 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 smoking for more than 6 months

DOCUMENTATION FOR INSULIN-EXPERIENCED PATIENTS

- Patient with type 1 diabetes is also on basal 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
 - Adverse reactions, such as injection site irritation
 - Lipohypertrophy
- Include the names of the rapid acting insulin and the date ranges they were tried

DOCUMENTATION FOR INSULIN-NAIVE PATIENTS

- Patient has tried at least two oral glucose lowering agents
- Rationale for why the patient cannot 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
- Include the names of the oral glucose lowering agents and the date ranges they were tried

SUBMITTING AN APPEAL

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. Refer to the rationale above and include chart notes when submitting an appeal.

CONSIDERATIONS FOR APPEALING PAYER DENIALS

Submitting a letter of appeal and/or medical necessity:

This will help to provide a clinical justification of a patient's need and appropriateness for Afrezza.

To download a template letter of appeal or medical necessity, visit www.afrezzahcp.com/resources

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PAYING FOR AFREZZA®

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

If your patient has **COMMERCIAL INSURANCE:**

- Eligible patients may pay as little as \$35 with the Afrezza Savings Card.
- For patient enrollment and full program terms and conditions, visit www.afrezzasavingscard.com.



If your patient has **MEDICARE PART D:**

Afrezza is included in the Inflation Reduction Act (IRA) \$35 insulin cap which took effect January 1, 2023. For patients with Medicare who are prescribed Afrezza, when a PA is completed and approved, they will pay no more than \$35 for a one-month supply of Afrezza.



JANUARY TO MAY 2023

If your patient is **DENIED COVERAGE:**

Options may exist to offset the cost of Afrezza if your patient is denied coverage, MannKind offers a Direct Purchase Program where eligible commercial patients may be able to get Afrezza for as little as \$99 per month.

For more information, and to see full terms and conditions, visit www.insulinsavings.com.



References:

1. Data on file, MannKind Corporation.

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PATIENT EDUCATION & TRAINING

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.

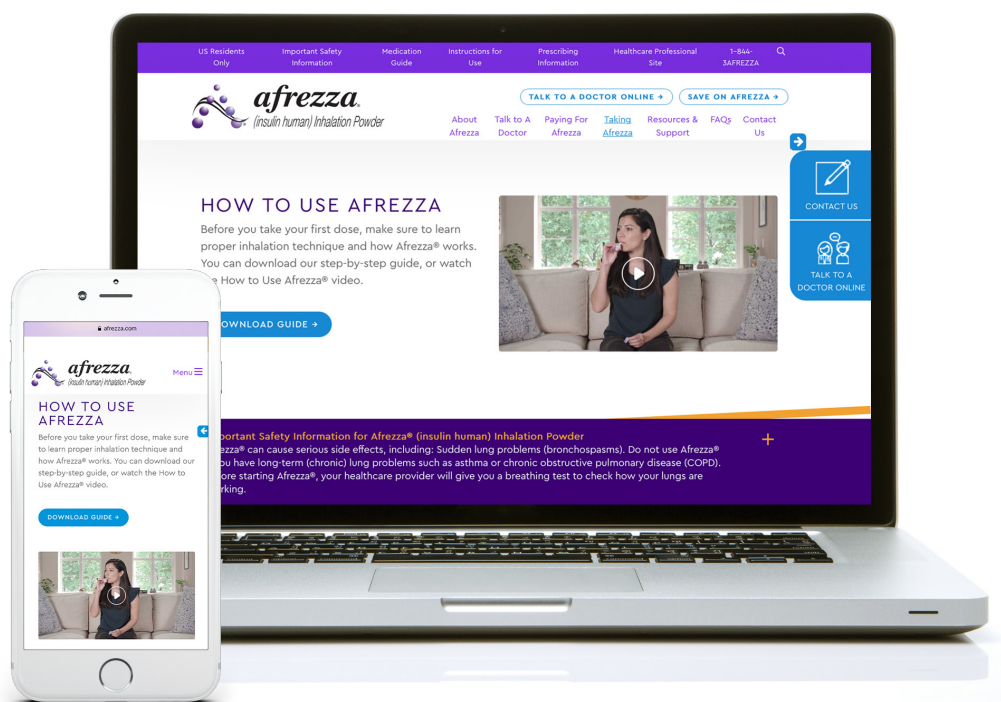
To initiate a training request, please complete the Afrezza Training Start Sheet, available through your Territory Business Manager. You may also have the patient call this number directly to schedule a training: 1-877-523-1199.

ONLINE SUPPORT AT AFREZZA.COM

We also offer patient support through our Virtual Training Center, which is accessible 24/7 on www.afrezza.com.

Virtual Training Center offers self-guided training videos to help patients start and stay on track with Afrezza.

Resource Library & FAQs provides patients with downloadable resources they need at their fingertips and a compilation of our most frequently asked questions.



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PATIENT FOLLOW-UP



The first follow-up visit after a patient starts using Afrezza is important.

Recommended Follow-Up Steps:

1. Assess the patient's post-prandial glucose excursions, and consider a dosing adjustment.
2. Ask if the patient has experienced a cough, and offer the suggestion of drinking a sip of water before inhaling Afrezza as a possible solution.¹
3. If you have additional questions that arise, contact your Afrezza Territory Business Manager for support.
4. Remember to conduct an FEV₁ test after six months, and annually thereafter to monitor lung function.

References:

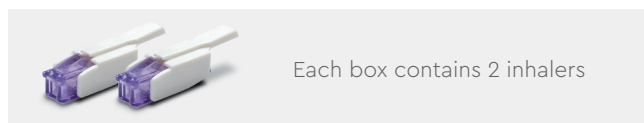
1. Levin P, Hoogwerf BJ, Snell-Bergeon J, Vigers T, Pyle L, Bromberger L. Ultra rapid-acting inhaled insulin improves glucose control in patients with type 2 diabetes mellitus. *Endocr Pract.* 2021;27(5):449-454.

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PRODUCT REFERENCE GUIDE

See below for a product reference guide, including all Afrezza NDC codes, their contents, and the maximum daily units per box.



COMBINATION BOX OPTIONS

SINGLE BOX OPTIONS

NDC	Afrezza Box Contents	1 Box (30-day supply)	2 Boxes (30-day supply)	3 Boxes (30-day supply)
 NDC 47918-0902- 18	Afrezza 4, 8 & 12 Unit Cartridges [60] 4-unit cartridges [60] 8-unit cartridges [60] 12-unit cartridges Total: 180 cartridges 1440 Afrezza Insulin Units	Total Insulin Units: 1440 Total Cartridges: 180 Max Total Daily Dose: 48 units	Total Insulin Units: 2880 Total Cartridges: 360 Max Total Daily Dose: 96 units	Total Insulin Units: 4320 Total Cartridges: 540 Max Total Daily Dose: 144 units
		Example Directions for Use: Inhale 4-16 units by mouth at mealtime and additional units as needed for glucose control. Max total daily dose ___ units.		
 NDC 47918-0880- 18	Afrezza 4 & 8 Unit Cartridges [90] 4-unit cartridges [90] 8-unit cartridges Total: 180 cartridges 1080 Afrezza Insulin Units	Total Insulin Units: 1080 Total Cartridges: 180 Max Total Daily Dose: 36 units	Total Insulin Units: 2160 Total Cartridges: 360 Max Total Daily Dose: 72 units	Total Insulin Units: 3240 Total Cartridges: 540 Max Total Daily Dose: 108 units
		Example Directions for Use: Inhale 4-12 units by mouth at mealtime and additional units as needed for glucose control. Max total daily dose ___ units.		
 NDC 47918-0898- 18	Afrezza 8 & 12 Unit Cartridges [90] 8-unit cartridges [90] 12-unit cartridges Total: 180 cartridges 1800 Afrezza Insulin Units	Total Insulin Units: 1800 Total Cartridges: 180 Max Total Daily Dose: 60 units	Total Insulin Units: 3600 Total Cartridges: 360 Max Total Daily Dose: 120 units	Total Insulin Units: 5400 Total Cartridges: 540 Max Total Daily Dose: 180 units
		Example Directions for Use: Inhale 8-12 units by mouth at mealtime and additional units as needed for glucose control. Max total daily dose ___ units.		
 NDC 47918-0874-90	Afrezza 4-Unit Cartridges [90] 4-unit cartridges Total: 90 cartridges 360 Afrezza Insulin Units	Total Insulin Units: 360 Total Cartridges: 90 Max Total Daily Dose: 12 units	Total Insulin Units: 720 Total Cartridges: 180 Max Total Daily Dose: 24 units	Total Insulin Units: 1080 Total Cartridges: 270 Max Total Daily Dose: 36 units
		Example Directions for Use: Inhale 4 units by mouth at mealtime and additional units as needed for glucose control. Max total daily dose ___ units.		
 NDC 47918-0878-90	Afrezza 8-Unit Cartridges [90] 8-unit cartridges Total: 90 cartridges 720 Afrezza Insulin Units	Total Insulin Units: 720 Total Cartridges: 90 Max Total Daily Dose: 24 units	Total Insulin Units: 1440 Total Cartridges: 180 Max Total Daily Dose: 48 units	Total Insulin Units: 2160 Total Cartridges: 270 Max Total Daily Dose: 72 units
		Example Directions for Use: Inhale 8 units by mouth at mealtime and additional units as needed for glucose control. Max total daily dose ___ units.		
 NDC 47918-0891-90	Afrezza 12-Unit Cartridges [90] 12-unit cartridges Total: 90 cartridges 1080 Afrezza Insulin Units	Total Insulin Units: 1080 Total Cartridges: 90 Max Total Daily Dose: 36 units	Total Insulin Units: 2160 Total Cartridges: 180 Max Total Daily Dose: 72 units	Total Insulin Units: 3240 Total Cartridges: 270 Max Total Daily Dose: 108 units
		Example Directions for Use: Inhale 12 units by mouth at mealtime and additional units as needed for glucose control. Max total daily dose ___ units.		

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Access and support made easier.

AfrezzaAssist® will help facilitate patient access to Afrezza®

YOUR PATIENTS WITH EITHER COMMERCIAL INSURANCE OR MEDICARE CAN PAY AS LITTLE AS \$35 OUT-OF-POCKET†

COMMERCIAL INSURANCE

Pay as little as
\$35 per month†

Eligible patients can enroll at
www.afrezzasavingscard.com

MEDICARE PART D

Pay no more than
\$35 per month††

Copay is only accessible
with approved coverage

†Subject to eligibility criteria and maximum benefit limitations. Additional cost savings (reduced copay) may be possible when combined with insurance coverage. See www.afrezzasavingscard.com for complete program terms and conditions.

††See www.medicare.gov/coverage/insulin for complete program terms and conditions.

If commercial insurance is denied, MannKind offers a Direct Purchase Program for \$99/box for a one month supply, or ~\$3 per day.*

*Applicable for most commercially insured patients whose prior authorization has been denied. 3-box maximum per month. \$99 per box.

To ensure your patients can access these options,
please submit prescriptions to AfrezzaAssist®

Submit the Rx to UBC Pharmacy, the AfrezzaAssist® Intake Pharmacy

UBC Pharmacy LLC, 600 Emerson Road Suite 300 Creve Coeur, MO 63141
NPI: 1962978858

AfrezzaAssist® will determine cost and coverage for your patients and coordinate fulfillment within the Afrezza Specialty Pharmacy Network or through a local pharmacy (if requested).**

**Prescription must be submitted to AfrezzaAssist (UBC Pharmacy) to access Direct Purchase Program option.



WEBSITE

<https://afrezahcp.com/afrezzaassist>



TELEPHONE (TOLL-FREE)

1-84 4-3 23- 7399
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