

PRIOR AUTHORIZATION CHECKLIST



The more organized and clear documentation is, the easier and faster it is for plans to evaluate appropriate Afrezza® patients.

DETAILED CLINICAL DOCUMENTATION IN THE PATIENTS' RECORD MAY:



Reduce prior authorization (PA) paperwork



Maximize practice resources



Shorten payer approval time

INCLUDE THE FOLLOWING DOCUMENTATION FOR PATIENTS WITH **TYPE 1 DIABETES**:

- Primary Diagnosis**
 - Type 1 diabetes mellitus
- Diagnostic findings**
 - Recent A1c (typically in the last 90 days)
 - Lung function test (FEV₁, baseline value and test date, typically within the last 30 days)
 - If the patient has tried Afrezza, remember to include PRE- and POST- Afrezza A1c results
- History of Other Diabetes Treatments**
 - For type 1, Afrezza must be used in combination with a long-acting insulin
 - Chart notes (EMR) indicating treatment/trial of other mealtime subcutaneous injectable insulins (dates/duration for each treatment, A1c level PRE- and POST- treatment)
- Medical History**
 - Chart notes (EMR) indicating if patient has lipohypertrophy, needle phobia, neuropathy, arthritis, or other physical or mental impairments to prevent successful injections
 - Chart notes (EMR) indicating if patient is non-compliant with injected rapid-acting insulin therapy due to inability or unwillingness to inject or intensify therapy
 - Non-smoker (documentation if recently stopped smoking within the last 6 months)
 - Afrezza should not be used in patients with chronic lung disease, such as COPD & asthma

INCLUDE THE FOLLOWING DOCUMENTATION FOR PATIENTS WITH **TYPE 2 DIABETES**:

- Primary Diagnosis**
 - Type 2 diabetes mellitus
- Diagnostic findings**
 - Recent A1c (typically in the last 90 days)
 - Lung function test (FEV₁, baseline value and test date, typically in the last 30 days)
 - If the patient has tried Afrezza, remember to include PRE- and POST- Afrezza A1c results
- History of Other Diabetes Treatments**
 - Chart notes (EMR) indicating treatment/trial of oral anti-diabetic medications (dates/duration for each treatment, A1c level PRE- and POST- treatment)
 - Chart notes (EMR) indicating treatment/trial of other mealtime subcutaneous injectable insulins (dates/duration for each treatment, A1c level PRE- and POST- treatment)
- Medical History**
 - Chart notes (EMR) indicating if patient has lipohypertrophy, needle phobia, neuropathy, arthritis, or other physical or mental impairments to prevent successful injections
 - Chart notes (EMR) indicating if patient is non-compliant with injected rapid-acting insulin therapy due to inability or unwillingness to inject or intensify therapy
 - Non-smoker (documentation if recently stopped smoking within the last 6 months)
 - Afrezza should not be used in patients with chronic lung disease, such as COPD & asthma

As a provider, you are solely responsible for billing third-party payers correctly, and you should determine if any payer-specific guidelines apply. The information provided here is general in nature and is not intended to be conclusive or exhaustive, nor is it intended to replace the guidance of a qualified professional advisor.

APPEAL CHECKLIST



Although it has already been determined that Afrezza® is an important therapy for the patient, an appeal may be a necessary step to obtain the product.

APPEAL STEPS	ACTIONS TO CONSIDER
1. Review the payer's denial letter	<ul style="list-style-type: none"> Understand the rationale for denial Identify appeal process requirements (documentation, timeframe, etc.)
2. Review original prior authorization (PA) request	<ul style="list-style-type: none"> Ensure that accurate and complete information was submitted (patient information, documentation, etc.)
3. Create a Letter of Appeal	<ul style="list-style-type: none"> Consider using the Letter of Appeal template provided by MannKind and found at www.Afrezzahcp.com/resources Make sure the letter includes demographic, diagnostic, and treatment information
4. Include all documentation required by the payer	<p>Supporting documentation may include:</p> <ul style="list-style-type: none"> Denial letter Letter of Appeal or Letter of Medical Necessity Medical Records or Chart Notes

CONSIDERATIONS FOR COMPLETING THE APPEAL



Each payer may have their own appeal requirements



The payer's denial letter will outline specifics regarding the appeal process and required documentation



Follow-up with a phone call to the payer after the appeal is submitted

The Letter of Appeal and Letter of Medical Necessity both offer the opportunity to explain why the patient is an appropriate candidate for Afrezza

LETTER OF APPEAL



Formally documents the request to appeal the payer's initial decision to deny coverage.

LETTER OF MEDICAL NECESSITY



Helps supplement the appeal with a detailed explanation in a narrative format



HCPs can visit Afrezzahcp.com/resources to find helpful templates like the Letter of Appeal and Letter of Medical Necessity.

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

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 Afrezza.com.