

PRIOR AUTHORIZATION CHECKLIST



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

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 basal 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.

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.

Full Prescribing Information, including **BOXED WARNING**, is available on Afrezzahcp.com, or from your MannKind representative.

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 (tried and failed plan formularies, etc.)• 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 https://afrezzahcp.com/coverage/• Make sure the letter includes demographic, diagnostic, and treatment information
4. Include all documentation required by the payer	Supporting documentation may include: <ul style="list-style-type: none">• Denial letter• Letter of Appeal or Letter of Medical Necessity• Medical Records or Chart Notes
5. Follow-up with the plan	Call the payer and follow up on the appeal. Keep in mind that each payer may have their own appeal requirements.

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

HCPs can visit [Afrezzahcp.com/coverage/](https://afrezzahcp.com/coverage/) to find helpful templates like the Letter of Appeal and Letter of Medical Necessity.



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

Important Safety Information

Indications and Usage

Afrezza (insulin human) Inhalation Powder is a rapid acting 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.

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.

Adverse Reactions

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

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