

**Inhaled Insulin (Afrezza)
Criteria for Use**

VA Pharmacy Benefits Management Services, Medical Advisory Panel and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD UTILIZE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

While not included in the criteria for use, it is appreciated that there may be exceptional circumstances where inhaled insulin may be needed for patients with psychological aversion to needles. Such a decision to use inhaled insulin must be made on a case-by-case basis.

Prior to considering inhaled insulin the following is recommended:

- Patient training with a VA Diabetes Educator
- Offer a trial of insulin pens, smaller gauge needles, and other assistive devices
- Patient must demonstrate competency with and agree to self-monitoring of blood glucose
- If the patient ultimately requires addition of basal insulin, conversion of pre-meal inhaled to injectable insulin should be made once the patient is stabilized on basal insulin and is comfortable with administering injections.

Exclusion Criteria

- COPD, asthma, or other chronic lung disorders
- Patients who smoke or who have recently quit smoking within the last six months*
- Active lung cancer, prior history of lung cancer, or risk factors (other than smoking) for lung cancer
- History of a serious hypersensitivity reaction to regular human insulin or excipients of Afrezza
- Treatment of diabetic ketoacidosis

*The 6-month time frame for those who have stopped smoking is based on the exclusion criteria for the Afrezza trial. However, providers may wish to consider a more conservative approach using the USPSTF guidance for annual lung cancer screening using low-dose CT scans in those considered to be at high risk for lung cancer defined as those 55-80 years old who have a ≥30 pack-year smoking history who have quit within the past 15 years.

Inclusion Criteria

- Patient has diabetes and requires insulin (inhaled insulin MUST be used in combination with long-acting insulin in patients with type 1 diabetes)
- Provider is experienced in managing insulin therapy in patients with diabetes (e.g., endocrinologists, diabetologists, practices in a diabetes management team)
- Patient MUST have baseline spirometry (within the last 6 months) to identify potential underlying lung disease

AND at least 1 of the following

- Severe persistent injection site reactions (e.g., lipohypertrophy)
- Works in an environment that does not allow needles

Dosage and Administration

Refer to product labeling for detailed information

Issues for Consideration

Monitoring of pulmonary function: After 6 months of therapy and annually thereafter even in the absence of pulmonary symptoms. Consider discontinuing inhaled insulin in patients who have a $\geq 20\%$ decline in FEV1 from baseline. In patients with pulmonary symptoms (e.g., wheezing, bronchospasm, breathing difficulties, persistent or recurring cough), consider more frequent monitoring of pulmonary function. If symptoms persist, discontinue inhaled insulin.

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