



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 11, 2020 October 2, 2023

AFREZZA® (insulin inhaled)

LENGTH OF AUTHORIZATION: UP TO 12 MONTHS

INITIAL REVIEW CRITERIA:

- Patient is 18 years of age or older; AND
- **Patient has diagnosis of type 1 diabetes mellitus or type 2 diabetes mellitus; AND**
- Patient has had previous treatment with a meal-time (e.g. prandial) insulin administered by subcutaneous injection (e.g. preparations containing insulin lispro, insulin aspart, insulin glulisine, or regular insulin); AND
- Patient has been assessed for pulmonary function (e.g., spirometry) before initiating, after 6 months of therapy, and annually, even in the absence of pulmonary symptoms (**confirmed by medical records**); AND
- Patient does not smoke; AND
- Patient does not have chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease); AND
- Patient does not have active lung cancer.

Type 1 diabetes mellitus

- Patient has not achieved goal HbA1c (<7%) after at least 90 days of treatment with injectable meal-time insulin (**confirmed by laboratory results**); AND
- Patient will be using Afrezza with a long-acting insulin (e.g. preparations containing insulin glargine, insulin detemir, insulin degludec, or insulin isophane).

Type 2 diabetes mellitus

- Patient has had previous treatment, contraindication, or intolerance with a metformin containing medicine; AND
- Patient has not achieved goal HbA1c (<7%) after at least 90 days of treatment with metformin and injectable meal-time insulin (**confirmed by laboratory results**).

CONTINUATION OF THERAPY:

- Patient has met the initial review requirements.
- Patient has been assessed for pulmonary function (e.g., spirometry); **confirmed by medical records**.
- Clinical response to therapy submitted (supporting documentation required).
- Dosage and administration does not exceed FDA approved maximum for the patient's indication.

DOSING AND ADMINISTRATION:

- **Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>**
- Available as 4 unit, 8 unit and 12 unit single use cartridges for inhalation.