Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	June 11, 2020

AFREZZA® (insulin inhaled)

LENGTH OF AUTHORIZATION: UP TO 12 MONTHS

REVIEW CRITERIA:

Type 1 diabetes mellitus

- Diagnosis of type 1 diabetes mellitus; AND
- Patient is 18 years of age or older; 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 not achieved goal HbA1c (<7%) after at least 90 days of treatment with injectable meal-time insulin; AND
- Patient will be using Afrezza with a long-acting insulin (e.g. preparations containing insulin glargine, insulin detemir, insulin degludec, or insulin isophane); 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; 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 2 diabetes mellitus

- Diagnosis of type 2 diabetes mellitus; AND
- Patient is 18 years of age or older; AND
- Patient has had previous treatment, contraindication, or intolerance with a metformin containing medicine; 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 not achieved goal HbA1c (<7%) after at least 90 days of treatment with metformin and injectable meal-time 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; 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.

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CONTINUATION OF THERAPY:

- Patient has met the initial review requirements.
- Patient has been assessed for pulmonary function (e.g., spirometry).
- 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:

Afrezza® should only be administered via oral inhalation using the Afrezza® Inhaler. Afrezza® is administered using a single inhalation per cartridge.

Insulin Naïve Patients

Individualize dose inhaled immediately before each meal; Start: 4 units inhaled immediately before each meal.

Insulin Experienced Patients

Individualize dose inhaled immediately before each meal; Start: individualize dose based on current prandial subcutaneous insulin intake.

Dosage form

Afrezza (insulin human) Inhalation Powder is available as 4 unit, 8 unit and 12 unit single use cartridges to be administered via oral inhalation with the Afrezza Inhaler only.