



UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2018 P 2056-4
Program	Prior Authorization/Medical Necessity
Medication	Afrezza (insulin human)
P&T Approval Date	7/2015, 7/2016, 4/2017, 5/2018
Effective Date	8/1/2018; Oxford only: 8/1/2018

**1. Background:**

Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Coverage criteria outlined below are for patients unable to self-inject short-acting insulin.

**2. Coverage Criteria:**

**A. Initial Authorization**

**1. Afrezza\*** will be approved based on **all** of the following criteria:

a. **One** of the following:

(1) Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump

**-OR-**

(2) Diagnosis of type 2 diabetes mellitus

**-AND-**

b. Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to **one** of the following:

(1) Physical impairment

(2) Visual impairment

(3) Lipohypertrophy

(4) Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria<sup>2</sup>)

**-AND-**

- c. FEV1 within the last 60 days is greater than or equal to 70% of expected normal as determined by the physician

**-AND-**

- d. Afrezza will **NOT** be approved in patients:

- (1) Who smoke cigarettes
- (2) Who recently quit smoking (within the past 6 months)
- (3) With chronic lung disease (e.g. asthma, chronic obstructive pulmonary disease)

**Initial authorization will be issued for 12 months**

## **B. Reauthorization**

1. **Afrezza** will be approved based on **both** of the following criteria:

- a. Repeat pulmonary function test confirms that patient has NOT experienced a decline of 20% or more in FEV1.

**-AND-**

- b. Patient continues to be unable to self-inject short-acting insulin due to **one** of the following:

- (1) Physical impairment
- (2) Visual impairment
- (3) Lipohypertrophy
- (4) Documented needle-phobia to the degree that the patient has previously refused any injectable therapy or medical procedure (refer to DSM-5 for specific phobia diagnostic criteria<sup>2</sup>)

**-AND-**

- c. Patient continues to not smoke cigarettes.

**Reauthorization will be issued for 12 months**

\*Typically excluded from coverage

**3. Additional Clinical Rules:**

- Supply limits may be in place

**4. References:**

1. Afrezza Prescribing Information. MannKind Corporation. September 2017.
2. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013.

Program	Prior Authorization/Medical Necessity – Afrezza
<b>Change Control</b>	
Date	Change
7/2015	New program.
7/2016	Annual review. Clarified that basal insulin could include continuous insulin pump.
4/2017	Removal of medical record requirement.
5/2018	Annual review. Updated references.