

Clinical Pharmacy Program Guidelines for Afrezza

Program	Prior Authorization
Medication	Afrezza (insulin human)
Issue Date	3/2015
Pharmacy and Therapeutics Approval Date	4/2017
Effective Date	6/2017

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:

<p>A. <u>Initial Authorization</u></p> <p>1. Afrezza will be approved based on <u>all</u> of the following criteria:</p> <p>a. <u>One</u> of the following:</p> <p style="padding-left: 40px;">(1) Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump</p> <p style="text-align: center;">-OR-</p> <p style="padding-left: 40px;">(2) Diagnosis of type 2 diabetes mellitus</p> <p style="text-align: center;">-AND-</p> <p>b. Patient is unable to self-inject medications (e.g. Humalog, Lantus, Levemir) due to <u>one</u> of the following:</p> <p style="padding-left: 40px;">(1) Physical impairment</p> <p style="padding-left: 40px;">(2) Visual impairment</p> <p style="padding-left: 40px;">(3) Lipohypertrophy</p> <p style="padding-left: 40px;">(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 criteria²)</p>
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-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 criteria²)

-AND-

- c. Patient continues to not smoke cigarettes.

Reauthorization will be issued for 12 months

3. References:

1. Afrezza Prescribing Information. MannKind Corporation, September 2016.
2. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition. Arlington, VA, American Psychiatric Association, 2013.

Program	Prior Authorization –Afrezza
Change Control	
Date	Change
3/2015	New program.
7/2016	Updated clinical criteria to align with Employer & Individual medical necessity policy. Updated policy to new template.
4/2017	Removal of medical record requirement