UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Afrezza

Program	Prior Authorization
Medication	Afrezza (insulin human)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	3/2015
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

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.

Afrezza has a black boxed warning for risk of acute bronchospasm in patients with chronic lung disease. Please see full prescribing information for additional details.

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[2])

-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[2])

-AND-

c. Patient continues to not smoke cigarettes

Reauthorization will be issued for 12 months

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Afrezza [package insert]. Danbury, CT: MannKind Corporation; October 2018.
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
5/2018	Annual review. Updated references.
6/2019	Annual review. Updated references.
6/2020	Annual review, added additional clinical rules and updated references.