UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2056- 7
Program	Prior Authorization/Medical Necessity
Medication	Afrezza (insulin human)
P&T Approval Date	7/2015, 7/2016, 4/2017, 5/2018, 6/2019, 6/2020, 7/2021
Effective Date	10/1/2021; Oxford only: 10/1/2021

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]:

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

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply

*Typically excluded from coverage

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; February 2020.
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
Change Control	
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.
6/2019	Annual review. Updated references.
6/2020	Annual review. Updated references. Added state mandate language.
7/2021	Annual review. Updated references.