UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2056-11
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, 2/2022, 2/2023, 2/2024, 4/2025
Effective Date	7/1/2025

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, Toujeo) due to **one** of the following[b]:

      (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[b]

      -AND-

d. Afrezza will **NOT** be approved in patients[b]:

(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[b]

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

[b] In Florida, Maine, and Tennessee only, medications prescribed for diabetes may be approved based on both of the following: 1) Provider attests use of this product is medically necessary for the treatment of diabetes; and- 2) If applicable, clinical characteristics exist that preclude the use of the covered preferred alternative(s) and use of the covered preferred alternative(s) could result in worsening of patient's condition or inadequate treatment (document alternatives and clinical information related to worsening/inadequate treatment).

*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 2023.
2. American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision. Arlington, VA, American Psychiatric Association, 2022.

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.
2/2022	Added Florida, Maine, and Tennessee mandate language.
2/2023	Annual review. Updated examples of self-injected medications.
2/2024	Annual review. Updated references. Updated state mandate language.
4/2025	Annual review with no changes.