

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

## Afrezza (insulin human) inhalation

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Package Description	Quantity Limit
Afrezza (insulin human) inhalation	90 cartridges (4 unit)	6 boxes per 30 days
	90 cartridges (8 unit)	4 boxes per 30 days
	90 cartridges (12 unit)	3 boxes per 30 days
	90 cartridges (60x4 unit and 30x8 unit)	6 boxes per 30 days
	90 cartridges (30x4 unit and 60x8 unit)	5 boxes per 30 days
	90 cartridges (60x8 unit and 30x12 unit)	4 boxes per 30 days
	180 cartridges (90x4 unit and 90x8 unit)	3 boxes per 30 days
	180 cartridges (60x4 unit and 60x8 unit and 60x12 unit)	2 boxes per 30 days
	180 cartridges (90x8 unit and 90x12 unit)	2 boxes per 30 days

### APPROVAL CRITERIA

Requests for Afrezza (insulin human) may be approved if the following criteria are met (either I, II) AND (III, IV and V):

- I. Individual has had a previous trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one preferred rapid-acting insulin (Admelog, authorized generic insulin lispro, authorized generic insulin aspart); **OR**
- II. Individual is requesting Afrezza and is unable or unwilling to administer injectable insulin.

#### **AND**

- III. Individual is 18 years of age or older; **AND**
- IV. Individual has a diagnosis of diabetes mellitus and one of the following:
  - A. For type 1 diabetes, individual will be using concurrently with long-acting insulin; **OR**
  - B. For type 2 diabetes, individual has inadequate control, intolerance, or contraindication to at least 2 oral anti-diabetic medications and will be using concurrently with long-acting insulin (AACE 2019);

#### **AND**

- V. Individual has had a physical examination including detailed medical history to identify potential lung disease.

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Afrezza (insulin human) may not be approved for the following:

- I. Individuals with a diagnosis of chronic lung disease, such as asthma or chronic obstructive pulmonary disease; **OR**
- II. Individuals who smoke cigarettes or who recently (within 6 months) quit smoking; **OR**
- III. As a treatment for diabetic ketoacidosis.

**Note:**

Afrezza (insulin human) has a black box warning for the risk of acute bronchospasm in individuals with chronic lung disease. Afrezza is contraindicated in individuals with chronic lung disease such as asthma or COPD. Acute bronchospasm has been observed in these individuals. Before initiating therapy, a detailed medical history, physical exam, and spirometry (FEV1) should be performed to identify potential lung disease.

**Key References:**

1. American Diabetes Association. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes - 2019. *Diabetes Care*. 2019;42: S90-S102.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 12, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Garber AJ, Abrahamson MJ, Barzilay JI, et. al. Consensus Statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the Comprehensive Type 2 Diabetes Management Algorithm – 2019 Executive Summary. *Endocrine Practice*. 2019;25:69-100.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. McCulloch DK. General principles of insulin therapy in diabetes mellitus. Last updated: September 20, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: September 28, 2019.
7. US Food and Drug Administration. FDA Drug Safety Communication: FDA revises warnings regarding use of the diabetes medicine metformin in certain patients with reduced kidney function. Last updated: November 14, 2017. Available at <https://www.fda.gov/Drugs/DrugSafety/ucm493244.htm>. Accessed: October 12, 2019.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.