



Antidiabetics – Inhaled Insulin (AFREZZA®)

WA.PHAR.34 Antidiabetics Inhaled Insulin (AFREZZA)

Background:

Insulin stimulates peripheral glucose uptake by inhibiting hepatic glucose production and glucose uptake by skeletal muscle and fat.

Inhaled insulin (AFREZZA®) is a self-administered, rapid-acting prandial insulin used to improve A1C in adult patients with type 1 or type 2 diabetes mellitus when used in combination with a basal insulin and/or oral antidiabetic medication(s). It is supplied as a dry powder and is administered via a breath-powered inhalation device.

Inhaled insulin is associated with significant safety risks that are not seen with injectable insulins, including a decline in pulmonary function and increased risk of acute bronchospasm. As a result, inhaled insulin is contraindicated in patients with underlying lung disease, such as asthma or COPD.

Medical necessity

Drug	Medical Necessity
Insulin human (AFREZZA®) Inhaled	Afrezza® inhaled insulin powder may be considered medically necessary when: Used for the treatment of type 1 or type 2 diabetes mellitus to improve glycemic control in adult patients who are unable to self-inject rapid-acting insulin.

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Insulin human (AFREZZA®) Inhaled	<p>Afrezza® inhaled insulin powder may be covered when ALL of the following are met:</p> <ol style="list-style-type: none"> ONE of the following: <ol style="list-style-type: none"> Diagnosis of type 1 diabetes mellitus and used in combination with a basal insulin or continuous insulin pump Diagnosis of type 2 diabetes mellitus History of failure (ineffective in reducing A1C to goal of 9% or less after 90 days), contraindication or intolerance to injectable insulin regimen containing a prandial insulin. Documentation of inability to self-inject medications FEV1 within the last 60 days in greater than or equal to (\geq) 70% of predicted as determined by prescriber NONE of the following: <ol style="list-style-type: none"> History of chronic lung disease (e.g. asthma or COPD) Current smoker/vaper <p>Approve for 6 months</p>

	Criteria (Reauthorization)
	<p>Afrezza® may be continued when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. Repeat pulmonary function test confirms that has NOT experienced a decline of 20% or more in FEV1 2. Continues documentation of inability to self-Inject medications 3. Continues not to smoke/vape <p>Approve for 12 months</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
4/8 unit combo (60x4 & 30x8)	5 boxes (2400 units)/30 days
4/8 unit combo (30x4 & 60x8)	6 boxes (3600 units)/30 days
4/8 unit combo (90x4 & 90x8)	3 boxes (3240 units)/30 days
8/12 unit combo (60X8 & 30X12)	4 boxes (3360 units)/30 days
90 cartridges (4 unit)	6 boxes (2160 units)/30 days

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