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IN BRIEF

An Expanded Indication for Afrezza

The rapid-acting inhaled human insulin *Afrezza* (MannKind), which was approved in 2014 for treatment of type 1 or type 2 diabetes in adults, has now been approved by the FDA for use in children ≥ 6 years old.¹

Pronunciation Key

Afrezza: uh frezz' uh

A CLINICAL STUDY — FDA approval of the expanded indication was based on the results of a double-blind noninferiority trial (INHALE-1) in 230 children 4-17 years old with type 1 (98%) or type 2 diabetes (2%) who were receiving

multiple daily insulin injections. Patients were randomized to receive inhaled insulin or a subcutaneous (SC) rapid-acting insulin analog, each in addition to basal insulin. At 26 weeks, the mean change from baseline in A1C was +0.19% with inhaled insulin and 0% with SC insulin. Inhaled insulin was associated with greater patient satisfaction and less weight gain than SC insulin.²

In an extension of the INHALE-1 trial, the mean change in A1C from 26 to 52 weeks was +0.38% in patients who continued using inhaled insulin and +0.31% in patients who switched from SC to inhaled insulin.³

DOSAGE AND ADMINISTRATION — *Afrezza* is packaged in blue, green, or yellow cartridges containing 4, 8, or 12 units, respectively, of rapid-acting insulin. One single-use cartridge

Table 1. Some Rapid-Acting Insulin Products

Drug	Concentration	Some Formulations	Onset	Peak	Duration	Cost ¹
Insulin inhalation powder – <i>Afrezza</i> (MannKind)	4, 8, 12 units/inh	4, 8, 12 unit cartridges	12 mins	~35-55 mins	1.5-3 hrs	\$487.50 ²
Insulin aspart – <i>NovoLog</i> (Novo Nordisk)	100 units/mL	3 mL cartridges, <i>FlexPen</i> ; 10 mL vials	10-30 mins	1-2 hrs	3-5 hrs	27.90
<i>Merilog</i> ³ (Sanofi)	100 units/mL	3 mL <i>SoloStar</i> pen; 10 mL vials				26.90
<i>Kirsty</i> ⁴ (Biocon)	100 units/mL	3 mL prefilled pen; 10 mL vials				26.90
<i>Fiasp</i> ⁵ (Novo Nordisk)	100 units/mL	3 mL <i>FlexTouch</i> pen; 10 mL vials	~2.5 mins	~63 mins	3-5 hrs	27.90
Insulin glulisine – <i>Apidra</i> (Sanofi)	100 units/mL	3 mL <i>SoloStar</i> pen; 10 mL vials	10-30 mins	60 mins	4-5 hrs	32.90
Insulin lispro – generic ⁶	100 units/mL	3 mL <i>KwikPen</i> ; 10 mL vials	10-30 mins	0.5-2 hrs	3-5 hrs	31.80
<i>Humalog</i> (Lilly)	100, 200 ⁷ units/mL	3 mL cartridges, <i>KwikPen</i> ; 3, 10 mL vials				31.80
<i>Admelog</i> ⁸ (Sanofi)	100 units/mL	3 mL <i>SoloStar</i> pen; 3, 10 mL vials				37.90
<i>Lyumjev</i> ⁹ (Lilly)	100, 200 units/mL	3 mL <i>KwikPen</i> ; 10 mL vials				31.80

1. Approximate WAC for one disposable pen in the lowest available concentration. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: Analysource® Monthly. October 5, 2026. Reprinted with permission by First Databank, Inc. All rights reserved. ©2026. www.fdbhealth.com/policies/drug-pricing-policy. Insulin products covered under Medicare part D are now capped at a maximum monthly out-of-pocket cost of \$35. Some manufacturers have capped the monthly out-of-pocket costs for their insulin products at \$35 for patients who have private health insurance.

2. Cost for one package containing 90 4-unit cartridges of *Afrezza* and 2 inhalers.

3. Biosimilar product not interchangeable with *NovoLog*.

4. Biosimilar product interchangeable with *NovoLog*.

5. Contains nicotinamide, which speeds initial absorption, and arginine, which increases stability. It is not interchangeable with *NovoLog*.

6. Authorized generic of *Humalog* manufactured by Lilly.

7. Only available as a prefilled, disposable pen.

8. A "follow-on" product similar to *Humalog*; it is not interchangeable with *Humalog*.

9. Contains citrate, which improves local vascular permeability, and treprostinil, which increases local vasodilation. It is not interchangeable with *Humalog*.

should be inserted into the palm-sized, breath-powered, dry-powder inhaler device. The drug is administered as a single inhalation. Doses >12 units require use of more than 1 cartridge. The inhaler must be replaced after 15 days.

Afrezza should be administered at the beginning of each meal. The recommended initial dose for insulin-naïve patients is 4 units per meal. For patients switching from SC insulin, the starting dose of *Afrezza* should be based on their current mealtime insulin dose rounded up to the nearest multiple of 4. *Afrezza* is contraindicated for use in patients with chronic lung disease such as asthma or COPD because of the risk of bronchospasm. It should not be used by patients who smoke or who stopped smoking <6 months earlier. ■

1. An inhaled insulin (*Afrezza*). *Med Lett Drugs Ther* 2015; 57:34.
2. MJ Haller et al. INHALE-1: a multicenter randomized trial of inhaled technosphere insulin in children with type 1 diabetes. *Diabetes Care* 2026; 49:179.
3. RW Beck et al. Inhaled technosphere insulin in children with diabetes: the INHALE-1 extension study. *Diabetes Technol Ther* 2026; 28:772.

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