



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

INHALED INSULIN

Generic	Brand	HICL	GCN	Exception/Other
INSULIN REGULAR, HUMAN	AFREZZA	00768		ROUTE = INHALATION

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

1. Does the patient meet any **ONE** of the following criteria?
  - Chronic lung disease (i.e., asthma or chronic obstructive pulmonary disease)
  - Active lung cancer
  - Currently in diabetic ketoacidosis
  - Patient who smokes or who has quit smoking within the past 6 months

If yes, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

If no, continue to #2.

2. Has baseline spirometry to measure FEV1 been performed?

If yes, continue to #3.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis type 1 diabetes and meet **ALL** of the following criteria?

- The patient is 18 years of age or older
- The patient is concurrently using a long-acting insulin
- The patient had a trial of a preferred formulary rapid acting insulin: Humalog

If yes, approve for 12 months by GPID with the following quantity limits:

- Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.
- Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.
- Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.
- Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.
- Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.
- Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.
- Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.
- Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.
- Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.

**APPROVAL TEXT:** Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter, and concurrent use of a long acting insulin. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

If no, continue to #4.

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INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of type 2 diabetes and meet **ALL** of the following criteria?
- The patient is 18 years of age or older
  - The patient had a trial of a preferred formulary rapid acting insulin: Humalog
  - The prescriber indicated that the patient is physically unable to or unwilling to administer injectable insulin

If yes, **approve for 12 months by GPID with the following quantity limits:**

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

**APPROVAL TEXT:** Renewal requires a follow-up spirometry after 6 months of treatment and annually thereafter. Renewal will not be provided for patients with a FEV1 that has declined 20% or more from baseline.

If no, do not approve.

**DENIAL TEXT:** See the initial denial text at the end of the guideline.

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INITIAL CRITERIA (CONTINUED)

**INITIAL DENIAL TEXT:** The guideline named **INHALED INSULIN (Afrezza)** requires a diagnosis of type 1 or type 2 diabetes, patient is 18 years of age or older, and a baseline spirometry to measure FEV1 is performed. In addition, the following criteria must be met:

**For type 1 diabetes, approval requires:**

- The patient is concurrently using a long-acting insulin
- The patient had a trial of a preferred formulary rapid acting insulin: Humalog

**For type 2 diabetes, approval requires:**

- The patient had a trial of a preferred formulary rapid acting insulin: Humalog
- The prescriber indicated that the patient is physically unable to or unwilling to administer injectable insulin

**Afrezza will NOT be approved for patients with any of the following conditions:**

- Chronic lung disease
- Active lung cancer
- Currently in diabetic ketoacidosis
- The patient is currently smoking or has quit smoking within the past 6 months

RENEWAL CRITERIA

1. Does the patient have a diagnosis of type 1 diabetes and currently on a long acting insulin?

If yes, continue to #3.

If no, continue to #2.

2. Does the patient have a diagnosis of type 2 diabetes?

If yes, continue to #3.

If no, do not approve.

**DENIAL TEXT:** See the renewal denial text at the end of the guideline.

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RENEWAL CRITERIA (CONTINUED)

3. Was follow-up spirometry to measure FEV1 performed after 6 months of treatment and annually thereafter?

If yes, continue to #4.

If no, **approve for 1 month by GPID (to allow for follow-up spirometry evaluation) with the following quantity limits:**

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

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RENEWAL CRITERIA (CONTINUED)

4. Has FEV1 declined 20% or more from baseline?

If yes, do not approve.

**RENEWAL DENIAL TEXT:** The guideline named **INHALED INSULIN (Afrezza)** requires a diagnosis of type 1 or type 2 diabetes, and a follow up spirometry to measure FEV1 after 6 months of treatment and annually thereafter. In addition, the following criteria must be met for renewal:

- **For type 1 diabetes**, approval requires concurrent use of a long acting insulin.
- **Afrezza will NOT be approved** for patients with a FEV1 that has declined 20% or more from baseline

If no, approve for 12 months by GPID with the following quantity limits:

- **Afrezza 90-4 Unit Cartridges (GPID 37619) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-8 Unit Cartridges (GPID 37621) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-12 Unit Cartridges (GPID 38918) for #180 cartridges (2 kits) per 28 days.**
- **Afrezza 90-4 Unit + 90-8 Unit Titration pack (GPID 37624) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 90-8 Unit + 90-12 Unit Cartridges (GPID 45955) for #180 cartridges (1 kit) per 28 days.**
- **Afrezza 30-4 Unit + 60-8 Unit Cartridges (GPID 37623) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 30-8 Unit Cartridges (GPID 37622) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-8 Unit + 30-12 Unit Cartridges (GPID 38923) for #360 cartridges (4 kits) per 28 days.**
- **Afrezza 60-4 Unit + 60-8 Unit + 60-12 Unit Cartridges (GPID 42833) for #180 cartridges (1 kit) per 28 days.**

**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Afrezza.

**REFERENCES**

- Afrezza [Prescribing Information]. Danbury, CT: Mankind Corporation. October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 02/25/19

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