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.

CONTINUED ON NEXT PAGE

INHALED INSULIN

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.

CONTINUED ON NEXT PAGE

INHALED INSULIN

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.

CONTINUED ON NEXT PAGE

INHALED INSULIN

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.

CONTINUED ON NEXT PAGE

INHALED INSULIN

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.**

CONTINUED ON NEXT PAGE

INHALED INSULIN

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
Created: 02/15
Client Approval: 02/19
P&T Approval: 07/17