Drug and Biologic Coverage Policy

Effective Date **2/1/2023**
Next Review Date **2/1/2024**
Coverage Policy Number **IP0533**

Afrezza®

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Related Coverage Resources

Insulins (Rapid Acting) - (IP0065)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for insulin human inhalation powder (Afrezza®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Insulin human inhalation powder (Afrezza) is considered medically necessary for the treatment of type 1 or type 2 diabetes mellitus when the individual meets ALL of the following criteria:

1. 18 years of age or older
2. Non-smoker or has stopped smoking more than 6 months prior to starting Afrezza
3. Absence of chronic lung disease, such as asthma or chronic obstructive pulmonary disease (COPD)
4. Documented intolerance or inability to administer injectable mealtime insulin (For example, physical impairment, visual impairment, lipohypertrophy)
5. One of the following:
    a. For individuals with type 1 diabetes mellitus, concurrent use of a long-acting insulin

b. For individuals with type 2 diabetes mellitus, inadequately controlled on TWO concurrent oral antihyperglycemics

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Continuation of Afrezza is considered medically necessary for type 1 or type 2 diabetes mellitus when initial criteria are met AND beneficial response is demonstrated.

Authorization Duration

Initial approval duration: up to 12 months
Reauthorization approval duration: up to 12 months

Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

Background

OVERVIEW

Afrezza is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

Limitations of Use:

- Afrezza is not a substitute for long-acting insulin. Afrezza must be used in combination with long-acting insulin in patients with type 1 diabetes mellitus.
- Afrezza is not recommended for the treatment of diabetic ketoacidosis.
- The safety and efficacy of Afrezza in patients who smoke has not been established. The use of Afrezza is not recommended in patients who smoke or who have recently stopped smoking.

Afrezza has a Boxed Warning regarding acute bronchospasm in patients with chronic lung disease. Prior to initiating therapy with Afrezza, patients should be evaluated with a physical exam and spirometry to identify underlying lung disease. Acute bronchospasm has been observed following Afrezza dosing in patients with asthma and in patients with COPD.

GUIDELINES

The American Diabetes Association (ADA) Standards of Medical Care in Diabetes are updated annually. The ADA Standards (2022) recommend most individuals with type 1 diabetes should be treated with multiple daily injections of prandial and basal insulin, or continuous subcutaneous insulin infusion. There are multiple approaches to insulin treatment; some form of insulin should be given in a planned regimen tailored to the individual patient. In type 2 diabetes, it is recognized that based on the progressive nature of the disease, insulin therapy is eventually indicated for many patients.

Regarding Afrezza, it is noted that studies in patients with type 1 diabetes suggest rapid pharmacokinetics. It is acknowledged that pilot study data suggest that supplemental doses of inhaled insulin taken based on postprandial glucose levels may improve blood glucose management without additional hypoglycemia or weight gain, although results from a larger study are needed for confirmation.

References

1. Afrezza® [prescribing information]. Danbury, CT: MannKind; February 2020.
2. American Diabetes Association. Standards of medical care in diabetes – 2022. Diabetes Care. 2022;45(Suppl 1):S1-S258.