RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Afrezza (insulin human) Inhalation Powder is a rapid-acting inhaled insulin indicated to improve glycemic control in adults with diabetes mellitus. Afrezza is a rapid-acting inhaled insulin that is administered at the beginning of each meal. 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 (1).

Regulatory status

FDA-approved indication: Afrezza is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus (1).

Limitations of Use (1):

- In patients with type 1 diabetes, must use with a long-acting insulin.
- Not recommended for the treatment of diabetic ketoacidosis.
- Not recommended in patients who smoke.

Afrezza carries a boxed warning regarding the risk of acute bronchospasm in patients with chronic lung disease. Afrezza is contraindicated in patients with chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD). Before initiating therapy with Afrezza, evaluate all patients with a detailed medical history, physical examination, and spirometry (FEV_1) to identify potential lung disease. Spirometry (FEV_1) should also be assessed after the first 6 months of therapy, and annually thereafter, even in the absence of pulmonary symptoms. In patients who have a decline of ≥ 20% in FEV_1 from baseline, consider discontinuing Afrezza (1).

The use of Afrezza during episodes of hypoglycemia is contraindicated. Hypoglycemia is the most common adverse reaction associated with insulin including Afrezza (1).

Safety and effectiveness in pediatric patients have not been established (1).

Summary

Afrezza is a rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus. Afrezza carries a boxed warning for risk of acute bronchospasm in patients with

chronic lung disease. Prior to initiating therapy, there should be a complete medical review to identify potential lung disease. Pulmonary function tests should be administered before initiating, after 6 months of therapy, and annually, even in the absence of pulmonary symptoms. Use of Afrezza is contraindicated during hypoglycemic episodes and in patients who have had hypersensitivity reactions to Afrezza or any of its excipients. The safety and efficacy of Afrezza in pediatric patients have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Afrezza while maintaining optimal therapeutic outcomes.

References

1. Afrezza [package insert]. Danbury, CT: MannKind Corporation; February 2023.