Type 2 Patients: Letter of Medical Necessity for Afrezza® (insulin human) Inhalation Powder

Payer Name: _____
Address: _____
Phone: _____
Fax: _____

RE: Patient Name: _____
Member ID: _____
Policy Group: _____
Date of Birth: _____
(mm/dd/yyyy)

_____
Date

Attn: _____,

Current standards of care for patients with type 2 diabetes focus on achieving and maintaining stringent glycemic goals. In an attempt to achieve these standards, the American Diabetes Association and the European Association for the Study of Diabetes issued a consensus algorithm for type 2 diabetes management that proposed the early use of insulin replacement as one therapeutic option.[1] Afrezza is the only FDA-approved ultra rapid-acting inhaled insulin indicated to improve glycemic control in adult patients with type 1 and type 2 diabetes mellitus.[2] Afrezza has demonstrated superior A1C reduction compared to Oral Glucose Lowering Agents (OAs) alone.[2,3] Twice as many type 2 patients treated with OAs plus Afrezza achieved A1C <7 versus OAs alone.[1,3] Afrezza can give type 2 patients improved mealtime control without the need for multiple daily injections.[1] Furthermore, the American Diabetes Association includes data on inhaled insulin (Afrezza®) in its current Standards of Medical Care in Diabetes, clearly indicating that inhaled insulin has a rapid peak and shortened duration of action compared with RAA and may cause less hypoglycemia and weight gain.[4]

My Patient, _____, is an appropriate candidate for Afrezza due to the fact that the patient is older than 18, a non-smoker, does not have any chronic lung diseases, and has already performed a recent spirometry (FEV_1) test on _____ with a baseline reading of_____. My Patient, _____ can't use the preferred injectable rapid-acting insulin because:

Please call my office at _____ if I can provide you with additional information to approve my request. If you have any additional questions regarding this request, please do not hesitate to contact the office. Thank you for your prompt attention to this matter.

Sincerely,

_____
Office Name:
Phone:

References: 1. David M. Nathan, John B. Buse, Mayer B. Davidson, Robert J. Heine, Rury R. Holman,Robert Sherwin, and Bernard Zinman. Management of Hyperglycemia in Type 2 Diabetes: A Consensus Algorithm for the Initiation and Adjustment of Therapy. Diabetes Care 2006 Aug; 29(8): 1963-1972. 2. Afrezza (insulin human) Inhalation Powder Prescribing Information. MannKind Corporation. 3. Rosenstock J, Franco D, Korpachev V, et al. Inhaled Technosphere insulin versus inhaled Technosphere placebo in insulin-naïve subjects with type 2 diabetes inadequately controlled on oral antidiabetes agent. Diabetes Care. 2015; 38(12):2274-2281. 4. Diabetes Care 2020 Jan; 43 (Supplement 1): S98-S110. https://doi.org/10.2337/dc20-S009.

These pages are for your reference only. Content on the pages below do not need to be sent to the insurance company.

INDICATION

Important Safety Information

WARNING: RISK OF ACUTE BRONCHOSPASM IN PATIENTS WITH CHRONIC LUNG DISEASE

- Acute bronchospasm has been observed in patients with asthma and COPD using AFREZZA.
- AFREZZA is contraindicated in patients with chronic lung disease such as asthma or COPD.
- Before initiating AFREZZA, perform a detailed medical history, physical examination, and spirometry (FEV_1) to identify potential lung disease in all patients.

Indications and Usage

Afrezza (insulin human) Inhalation Powder 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 have not been established. The use of AFREZZA is not recommended in patients who smoke or who have recently stopped smoking (less than 6 months).**

Contraindications

AFREZZA is contraindicated in patients:

- During episodes of hypoglycemia
- With chronic lung disease (such as asthma or chronic obstructive pulmonary disease [COPD]) because of the risk of acute bronchospasm
- With hypersensitivity to regular human insulin or any of the AFREZZA excipients

Warnings and Precautions

Acute Bronchospasm: Before initiating therapy, evaluate patients with a medical history, physical examination and spirometry (FEV_1) to identify potential underlying lung disease. Acute bronchospasm has been observed following AFREZZA dosing in patients with asthma and patients with COPD. The long-term safety and efficacy of AFREZZA in patients with chronic lung disease have not been established.

Changes in Insulin Regimen: Monitor blood glucose in all patients treated with insulin. Modify insulin regimen and dose cautiously and only under medical supervision. Changes in insulin strength, manufacturer, type, or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment to help mitigate the risk of hypoglycemia or hyperglycemia.

Hypoglycemia: Hypoglycemia is the most common adverse reaction of insulin therapy, including AFREZZA, and may be serious and life-threatening. Educate patients and caregivers on mitigating the risks associated with hypoglycemia. Increased frequency of blood glucose monitoring is recommended for patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia.

Decline in Pulmonary Function: AFREZZA has been shown to cause a decrease in lung function as measured by FEV_1. In clinical trials lasting up to 2 years, AFREZZA treated patients experienced a small (40 mL) but greater FEV_1 decline than comparator-treated patients. Assess pulmonary function with spirometry at baseline, after the initial 6 months of therapy and annually thereafter even in the absence of pulmonary symptoms.

Consider more frequent lung function assessment in patients with pulmonary symptoms, e.g., wheezing, bronchospasm, breathing difficulties, or persistent or recurring cough. If symptoms persist, discontinue AFREZZA.

Lung Cancer: In clinical trials, 2 cases of lung cancer were reported in patients exposed to AFREZZA while no cases were reported for the comparators. In both cases, a prior history of heavy tobacco use was identified as a risk factor for lung cancer. Two additional cases of lung cancer (squamous cell and lung blastoma) were reported in non-smokers exposed to AFREZZA after the trial completion. These data are insufficient to determine whether AFREZZA has an effect on lung or respiratory tract tumors. In patients with active lung cancer, a prior history of lung cancer, or in patients at risk of lung cancer, consider whether the benefits of AFREZZA outweigh the risks.

Diabetic Ketoacidosis (DKA): Increase the frequency of glucose monitoring and consider an alternate route of administration of insulin in patients at risk for DKA.

Hypersensitivity Reactions: Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including AFREZZA. If hypersensitivity reactions occur, discontinue AFREZZA, treat per standard of care and monitor if indicated.

Hypokalemia: Closely monitor potassium levels in patients at risk of hypokalemia and treat if indicated.

Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs): Fluid retention, which may lead to or exacerbate heart failure, can occur with concomitant use of TZDs and insulin. Observe these patients for signs and symptoms of heart failure. If heart failure occurs, manage according to current standards and consider TZD dose reduction or discontinuation.

Adverse Reactions

The most common adverse reactions associated with AFREZZA (2% or greater incidence) are hypoglycemia, cough, and throat pain or irritation.

Drug Interactions

Certain drugs may affect glucose metabolism, increasing the risk of hypoglycemia or decreasing the blood glucose lowering effect of AFREZZA. Dose adjustment and increased frequency of blood glucose monitoring may be required. Co-administration of beta-blockers, clonidine, guanethidine, and reserpine with AFREZZA may reduce the signs and symptoms of hypoglycemia. For full list, please see Full Prescribing Information.

Please see Afrezza Full Prescribing Information, including **BOXED WARNING** by visiting www.afrezza.com