

DRUG APPROVAL

Exubera[®] (insulin human (rDNA origin))

Exubera (insulin human [rDNA origin], Pfizer Inc) is an inhaled form of insulin that was approved by the U.S. Food and Drug Administration (FDA) on January 27, 2006, for the treatment of adult patients with diabetes mellitus for the control of hyperglycemia (high blood sugar).^{1,2} Exubera starts working in about 10 to 20 minutes, or about the same amount of time as rapid-acting insulins, like Humalog[®] (insulin lispro, rDNA origin, Eli Lilly and Company) and NovoLog[®] (insulin aspart [rDNA origin], NovoNordisk Inc.). Exubera works faster than regular human insulin to lower blood sugar levels. For this reason, Exubera should be given right before a meal. Exubera lowers blood sugar levels for about six hours. This is comparable to regular human insulin. In patients with type 1 diabetes, Exubera should be used in regimens that include a longer-acting insulin. In patients with type 2 diabetes, Exubera can be used by itself or in combination with oral diabetes medications or longer-acting insulins. Since Exubera may affect lung function, patients should have their lungs tested before starting Exubera and while they are using it (after the first six months of therapy and then annually). Exubera should not be used by people who smoke or who have quit smoking within the last six months. It is also not recommended to be used by people who have lung disease, such as asthma or chronic obstructive pulmonary disease (COPD). Side effects that may occur with Exubera include low blood sugar, cough, dry mouth, and chest pain. Exubera is available in 1 mg and 3 mg "blisters," which are small foil packets containing insulin powder. The "blisters" are used with the Exubera Inhaler to deliver the medication into the lungs.² Exubera is expected to launch in the second quarter of 2006.¹

BACKGROUND

Diabetes mellitus occurs when the body has trouble changing food into energy. This causes blood sugar levels to become higher than normal. Over time, high blood sugar levels may damage nerves and blood vessels. This can lead to heart disease, stroke, kidney problems, blindness, nerve problems, gum infections, and amputation.³ To date, approximately 18 million people in the United States, or 6.3% of the population, have diabetes.⁴ According to the Centers for Disease Control and Prevention, diabetes is the sixth leading cause of death in the United States.⁵ The total healthcare costs of a patient with diabetes in the United States are between two and three times that of a person without the condition.⁶ In 2002, it was estimated that direct medical costs for diabetes in the United States were \$92 billion and indirect costs (e.g., short-term and permanent disability and premature mortality) were \$40 billion.⁷

ANTICIPATED BUDGET IMPACT

Caremark estimates that Exubera will increase pharmacy budgets between \$0.02 and \$0.03 Per Member Per Month (between \$0.26 to \$0.42 Per Member Per Year) during its first year on the market.⁸ It is also anticipated that Exubera will have a greater market penetration in the type 2 diabetes market relative to the type 1 market.⁹⁻¹¹ Exubera will likely capture a niche group of patients who are wanting to avoid injections but will exclude a substantial subset (approximately 25%) of the diabetes population who are either asthmatics or smokers.¹⁰ In the next several years, newer diabetes therapies are poised to enter the market; these new therapies will compete with Exubera for the same patient base. Caremark will continue to monitor the long-term budget effects of Exubera's introduction into the pharmaceutical marketplace. The actual pharmacy budget impact will vary depending on your population's current use of medications for diabetes.

Consult with your Caremark account representative on the best approach to manage Exubera in your population.

CAREMARK RESPONSE

Based on currently available data, Caremark recommends for your consideration, and at your discretion, coverage of Exubera when your prescription benefit plan also covers other insulins for the treatment of diabetes mellitus. Caremark recognizes the unique needs of plan participants with diabetes. Plan participants requiring Exubera may be good candidates for the CarePatterns[®] Health Management Program for Diabetes. This disease management program helps plan participants with diabetes to better manage their condition, and reinforces the importance of medication compliance, which may lead to overall decreased healthcare costs and improved outcomes. Concurrent and retrospective utilization review programs are available for Exubera, as well as selected utilization management programs.

Caremark will monitor the use of Exubera to determine if any additional clinical programs are needed.

CAREMARK CONTACT

For more information call your Caremark account representative.

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only, and is based in part on information derived from third parties.

References

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