

## Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

### **Therapeutic Class:**

Inhaled Insulins

### **Overview:**

Exubera™ is FDA approved for the treatment of adult patients with diabetes mellitus for the control of hyperglycemia. It has an onset of action similar to rapid-acting insulin analogs and a duration comparable to subcutaneously administered regular human insulin. Exubera™ should be used in regimens that include a longer-acting insulin for patients with type 1 diabetes. Exubera™ is indicated as monotherapy and in combination with oral agents or longer-acting insulins for patients with type 2 diabetes. Exubera™ exerts its activity by regulating glucose metabolism. It lowers blood glucose concentrations by stimulating peripheral glucose uptake by skeletal muscle and fat and by inhibiting hepatic glucose production. Exubera™ also inhibits lipolysis in the adipocyte, inhibits proteolysis, and enhances protein synthesis.

The most common adverse events associated with Exubera™ in clinical trials include the following: hypoglycemia, chest pain, xerostomia, respiratory tract infection, cough, sputum increased, bronchitis, and dyspnea. Although mild to moderate cough occurred more frequently in patients who received inhaled insulin in clinical trials, the incidence of cough declines with continued therapy. The peak concentration and total systemic exposure over 6 hours are 2 to 3 times greater and the time-to-peak concentration earlier in patients who smoke compared to those who are non-smokers. Therefore, patients who smoke or who have discontinued smoking less than 6 months prior to starting therapy should not receive Exubera™. Exubera™ is also contraindicated in patients with unstable or poorly controlled lung disease, due to wide variations in lung function that could affect the absorption of the insulin and increase the risk of hyperglycemia or hypoglycemia.

Inhaled insulin appears to be equally efficacious to regular human insulin in clinical trials when administered in combination with long-acting subcutaneous insulin in patients with type 1 diabetes. It has not been compared with insulin aspart or insulin lispro regimens, which have more similar pharmacokinetic and pharmacodynamic profiles to Exubera™. Results from clinical trials support that inhaled insulin offers an alternative to short-acting subcutaneous insulin when used in combination with oral agents. Exubera™ is also an alternative to short-acting subcutaneous insulin when used in conjunction with longer-acting basal insulin for patients with type 2 diabetes.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Manufacturer</b>
Insulin human [rDNA origin] inhalation powder	Exubera™	Pfizer

**Summary:** The convenient formulation of Exubera™ may allow more aggressive insulin therapy in some patients who find increased use of the injectable short-acting insulin inconvenient or unacceptable. Exubera™ is available in 1- and 3-mg blister packs for inhalation with the Exubera™ Inhaler, which are approximately equivalent to 3 and 8 units of subcutaneously injected regular human insulin, respectively. Exubera™ should be administered immediately prior to meals. Selection for the preferred drug list should be based upon efficacy, safety, availability, and cost.