

Coverage of Artificial Pancreas Systems in Type 1 Diabetes

Artificial pancreas (AP) systems are composed of insulin pumps, continuous glucose monitors and smart software to automate the delivery of the right amount of insulin at the right time. The first AP system was approved by the FDA in September of 2016 and is the first ever approved to automate dosing of basal insulin to reduce both high and low blood sugar levels. Published clinical evidence demonstrates that automating insulin delivery improves glycemic outcomes, including hemoglobin A1c (HbA1c) and hypoglycemia. Based on the evidence of clinical benefit and analyses indicating cost-effectiveness, JDRF strongly urges health plans and other payers to provide coverage for artificial pancreas (AP) systems for those with type 1 diabetes (T1D) consistent with the labeled indications.

ARTIFICIAL PANCREAS SYSTEM SAFELY IMPROVES GLYCEMIC OUTCOMES

In a multicenter pivotal trial described by Garg *et al.*, the Medtronic MiniMed® 670G system was shown to safely improve glycemic outcomes in adolescents (n=30, ages 14-21 years) and adults (n=94, ages 22-75 years) with type 1 diabetes. Compared to baseline, study-end HbA1c levels were significantly lower in both adolescents and adults. Specifically, adolescent HbA1c levels decreased from 7.7% ± 0.8% to 7.1% ± 0.6% (p<0.001) and adult HbA1c levels decreased from 7.3% ± 0.9% to 6.8% ± 0.6% (p<0.001). Moreover, the study demonstrated that use of the Medtronic MiniMed® 670G system, increased the percent of sensor glucose values in-target (71-180 mg/dL). These results were achieved without any episodes of severe hypoglycemia or diabetic ketoacidosis (DKA) in over 12,000 patient-days of use.¹

A 2016 study by Bergenstal *et al.* involved 123 individuals, aged 14-75 who had Type 1 diabetes. These people wore the MiniMed® 670G system for approximately 3.5 months. HbA1c levels improved from 7.4% at baseline to 6.9% at the completion of the study period. The percentage of sensor glucose values within the target range changed from 66.7% at baseline to 72.2% at study end.²

COVERAGE FOR AP SYSTEMS

Many more AP systems are in the pipeline and are expected to be on the market in 2017 and 2018. Based on clinical evidence of safety, effectiveness, and cost-savings, JDRF urges payers to support coverage of AP systems for people with type 1 diabetes.

¹ Garg et al (2017). Glucose Outcomes with the In-Home Use of a Hybrid Closed-Loop Insulin Delivery System in Adolescents and Adults with Type 1 Diabetes. *Diabetes Technology and Therapeutics, Volume 19, No 13, DOI: 10.1089/dia.2016.0421.*

² Bergenstal RM, Garg S, Weinzimer SA, et al. Safety of a hybrid closed-loop insulin delivery system in patients with Type 1 diabetes. *JAMA.* 2016; 316(13):1407-1408.

ABOUT T1D

Type 1 diabetes is an autoimmune disease in which a person's pancreas stops producing insulin, a hormone that enables people to get energy from food. It occurs when the body's immune system attacks and destroys the insulin-producing cells in the pancreas. Its onset has nothing to do with diet or lifestyle, and cannot currently be prevented or cured.

Type 1 diabetes comes on suddenly, and causes dependence on injected or pumped insulin for life. Living with T1D is a constant challenge. People with the disease must carefully balance insulin doses (either by injections multiple times a day or continuous infusion through a pump) with eating and daily activities throughout the day and night. They must also test their blood sugar by pricking their fingers for blood six or more times a day. Despite this constant attention, people with T1D still run the risk of dangerous high or low blood sugar levels, both of which can be life-threatening.

While insulin injections or infusion allow a person with T1D to stay alive, they do not cure the disease, nor do they necessarily prevent the possibility of the disease's serious effects. Diabetes increases the risk of heart attack or stroke by 2-4 times, and is the leading cause of kidney failure, blindness in working age adults, and amputations not related to injury.

ABOUT JDRF

JDRF is the leading global organization funding type 1 diabetes (T1D) research. Our mission is to accelerate life-changing breakthroughs to cure, prevent and treat T1D and its complications. To accomplish this, JDRF has invested nearly \$2 billion in research funding since our inception. We are an organization built on a grassroots model of people connecting in their local communities, collaborating regionally for efficiency and broader fundraising impact, and uniting on a national stage to pool resources, passion, and energy. We collaborate with academic institutions, policymakers, and corporate and industry partners to develop and deliver a pipeline of innovative therapies to people living with T1D. Our staff and volunteers in more than 100 locations throughout the United States and our six international affiliates are dedicated to advocacy, community engagement and our vision of a world without T1D. For more information, please visit jdrf.org or follow us on Twitter: @JDRF.