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IN BRIEF

A New Glucagon Injection *(Gvoke)* for Severe Hypoglycemia

The FDA has approved a new formulation of glucagon (*Gvoke* – Xeris) for subcutaneous treatment of severe hypoglycemia in patients ≥2 years old with diabetes. Conscious patients with symptoms of hypoglycemia can take oral glucose. Glucagon is usually administered by a caregiver to an unresponsive patient. The new formulation is available in a single-use prefilled syringe *(Gvoke PFS)* and is expected to become available in a single-use auto-injector *(Gvoke HypoPen)* in 2020. Unlike previously available injectable glucagon products (*Glucagon Emergency Kit*, and others), *Gvoke* does not require reconstitution before administration. A glucagon nasal powder *(Baqsimi)* that does not require coordination with inhalation was recently approved for use in patients ≥4 years old.[1]

Pronunciation Key
Gvoke: gee' voke

FDA approval of *Gvoke* was based on the results of two unpublished, randomized, crossover trials in a total of 161 adults and one single-arm trial in 31 children ≥2 years old with type 1 diabetes (available as abstracts and summarized in the package insert). Patients were given a continuous insulin infusion to reduce their blood glucose to <50 mg/dL (adult studies) or <80 mg/dL (pediatric study) and then treated subcutaneously with glucagon from *Gvoke HypoPen* or *Glucagon Emergency Kit* (all pediatric patients received *Gvoke*). In the adult studies, treatment success, defined as an increase in blood glucose of ≥20 mg/dL or to >70 mg/dL at 30 minutes after administration, was achieved in 99% of patients with *Gvoke* and in 100% with *Glucagon Emergency Kit*; the mean time to relief of symptoms in the two groups was similar.[2,3] In the pediatric study, 100% of patients had an increase in blood glucose of ≥25 mg/dL, the primary endpoint.[4] As with other glucagon formulations, the most common adverse effects of *Gvoke* were nausea and vomiting.

In a crossover ease-of-use trial, 14 of 16 adults successfully used *Gvoke PFS* under simulated real-world conditions; 5 successfully used *Glucagon Emergency Kit*.[5] In two validation studies, 148 of 150 adults and adolescents (99%) successfully used *Gvoke HypoPen* or *Gvoke PFS*. The mean time required for preparation and administration was 60-70 seconds shorter with *Gvoke* than with *Glucagon Emergency Kit*.[5,6]

Table 1. Some Glucagon Products

Drug	Formulations	Cost[1]
Powder for injection – *Glucagon Emergency Kit* (Lilly)	1 mg powder with 1 mL diluent	$280.80
GlucaGen HypoKit (Novo Nordisk)		282.10
Injection – *Gvoke PFS* (Xeris)	0.5 mg/0.1 mL, 1 mg/0.2 mL prefilled syringes	280.80
Gvoke HypoPen	0.5 mg/0.1 mL, 1 mg/0.2 mL autoinjectors	N.A.
Nasal powder – *Baqsimi* (Lilly)	3 mg intranasal device	280.80

N.A. = not yet available; expected to become available in 2020
1. Approximate WAC for a single dose. WAC = wholesaler acquisition cost or manufacturer's published price to wholesalers; WAC represents a published catalogue or list price and may not represent an actual transactional price. Source: AnalySource® Monthly. October 5, 2019. Reprinted with permission by First Databank, Inc. All rights reserved. ©2019. www.fdbhealth.com/policies/drug-pricing-policy.

Children <12 years old weighing <45 kg should be given a 0.5-mg dose of *Gvoke*; all other patients should receive 1 mg. The drug should be injected subcutaneously into the lower abdomen, outer thigh, or outer upper arm. Emergency medical services should be called immediately after a dose is given. If there is no response to the first dose, a second dose can be given 15 minutes later. ■

1. Glucagon nasal powder (Baqsimi) for severe hypoglycemia. Med Lett Drugs Ther 2019; 61:148.
2. MP Christiansen et al. A phase 3 comparison of a novel liquid glucagon autoinjector to glucagon emergency kit for the symptomatic relief of severe hypoglycemia. Presented at the American Diabetes Association's 78th Scientific Sessions, June 22-26, 2018, Orlando, FL. Available at: http://bit.ly/2ClKfgm. Accessed November 7, 2019.
3. MP Christiansen et al. A phase 3 comparison of a novel liquid glucagon autoinjector to glucagon emergency kit for the treatment of severe hypoglycemia. Presented at the American Diabetes Association's 78th Scientific Sessions, June 22-26, 2018, Orlando, FL. Available at: http://bit.ly/32kFRsv. Accessed November 7, 2019.
4. B Buckingham et al. Liquid room temperature stable glucagon—glucose response in pediatric type 1 diabetes patients. Presented at the American Diabetes Association's 78th Scientific Sessions, June 22-26, 2018, Orlando, FL. Available at: http://bit.ly/2qpxclj. Accessed November 7, 2019.
5. V Valentine et al. Human factors usability and validation studies of a glucagon autoinjector in a simulated severe hypoglycemia rescue situation. Diabetes Technol Ther 2019; 21:522.
6. B Newswanger et al. Human factors studies of a prefilled syringe with stable liquid glucagon in a simulated severe hypoglycemia rescue situation. Expert Opin Drug Deliv 2019; 16:1015.

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