Gvoke HypoPen™ (glucagon injection)

Prior Authorization (PA) Checklist

The checklist below highlights information that may be helpful to include when completing a prior authorization form:

- **Complete the plan specific PA form**

- Include the clinical rationale for the treatment, which should include any history of prior severe hypoglycemia, prior history of failure to correctly administer conventional kits (lack of dexterity, unable to open, poor visual/cannot read instructions, poor memory, become agitated /panicked low health literacy), disease history, ER visits, hospitalizations, impairments, comorbidities, and any other clinical documentation for treatment.
  - **Include explanation that Gvoke HypoPen™ is a medication that is used for emergency rescue situations for severe hypoglycemia**

- Summary of the patient's diagnosis and history
  - Diagnosis code (Example: Type 1 E10.649 or Type 2 E11.649) and date of diagnosis
  - Patient medical records
  - Patient's current diabetes treatment regimen that may increase risk of severe hypoglycemia
  - Previously administered/attempted treatments
    - Glucagon Emergency Kit (injection)
    - GlucaGen® HypoKit® (injection)
    - Proglycem® (diazoxide)
    - Glucose tablets
  - Recent symptoms and conditions
  - Prescriber's medical opinion on status of patient's condition

- Additional information to include:
  - Patient name, date of birth and insurance policy information
  - Physician name, provider ID number and tax ID number
  - Procedure and HCPCS codes for products/services to be provided
  - For Medicare patients, consider using the plan specific Coverage Determination form, which can be found in CoverMyMeds®
  - Information regarding the treatment decision to prescribe Gvoke HypoPen:
    - Indication: Gvoke™ is indicated for the treatment of severe hypoglycemia in pediatric and adult patients aged 2 years and above.
    - ADA National Guidelines for glucagon use

- If needed, see below for links to Medical Necessity and Medical Exception letter templates
  - Medical Exception letter template
  - Medical Necessity template

- **If the PA is initially rejected, submit the PA again**

ASPN (Xeris Support Program)
Hub program that offers support with:

- electronic benefits verification
- electronic prior authorizations (if needed)
- automatic application of copay for eligible patients
- patient choice of local pharmacy or home delivery option
- prescription refill reminders

Select "ASPN" in the EHR. By selecting the ASPN Pharmacy at the address below, the prescription will be immediately routed to the Xeris Support Program team.
ASPN Pharmacies LLC.
200 Park Avenue, Suite 300
Florham Park, NJ 07932
NPI: 1538590690 | NCPDP: 3147863

INDICATION AND IMPORTANT SAFETY INFORMATION

GVOKE is indicated for the treatment of severe hypoglycemia in adult and pediatric patients with diabetes ages 2 years and above.

IMPORTANT SAFETY INFORMATION

Contraindications

GVOKE is contraindicated in patients with pheochromocytoma, insulinoma, and known hypersensitivity to glucagon or to any of the excipients in GVOKE. Allergic reactions have been reported with glucagon and include anaphylactic shock with breathing difficulties and hypotension.

Warnings and Precautions

GVOKE is contraindicated in patients with pheochromocytoma because glucagon may stimulate the release of catecholamines from the tumor. If the patient develops a dramatic increase in blood pressure and a previously undiagnosed pheochromocytoma is suspected, 5 to 10 mg of phentolamine mesylate, administered intravenously, has been shown to be effective in lowering blood pressure.

In patients with insulinoma, administration of glucagon may produce an initial increase in blood glucose; however, GVOKE administration may directly or indirectly (through an initial rise in blood glucose) stimulate exaggerated insulin release from an insulinoma and cause hypoglycemia. GVOKE is contraindicated in patients with insulinoma. If a patient develops symptoms of hypoglycemia after a dose of GVOKE, give glucose orally or intravenously.
Allergic reactions have been reported with glucagon. These include generalized rash, and in some cases, anaphylactic shock with breathing difficulties and hypotension. GVOKE is contraindicated in patients with a prior hypersensitivity reaction.

GVOKE is effective in treating hypoglycemia only if sufficient hepatic glycogen is present. Patients in states of starvation, with adrenal insufficiency or chronic hypoglycemia, may not have adequate levels of hepatic glycogen for GVOKE administration to be effective. Patients with these conditions should be treated with glucose.

Necrolytic migratory erythema (NME), a skin rash commonly associated with glucagonomas has been reported postmarketing following continuous glucagon infusion and resolved with discontinuation of the glucagon. Should NME occur, consider whether the benefits of continuous glucagon infusion outweigh the risks. Glucagon administered to patients with glucagonoma may cause secondary hypoglycemia.

Adverse Reactions

Most common (≥5%) adverse reactions associated with GVOKE are nausea, vomiting, injection site edema (raised 1 mm or greater), and hypoglycemia.

Drug Interactions

Patients taking beta-blockers may have a transient increase in pulse and blood pressure when given GVOKE. In patients taking indomethacin, GVOKE may lose its ability to raise blood glucose or may even produce hypoglycemia. GVOKE may increase the anticoagulant effect of warfarin.

Click here for full Prescribing Information

xeris PHARMACEUTICALS