LABEL NAME	MANUFACTURER	DRUG TYPE	PROVIDER SYNERGIES BRAND NAME ROUTE
BAQSIMI 3 MG SPRAY	ELI LILLY & CO.	SSB	BAQSIMI (NASAL)
BAQSIMI 3 MG SPRAY ONE PACK	ELI LILLY & CO.	SSB	BAQSIMI (NASAL)
BAQSIMI 3 MG SPRAY TWO PACK	ELI LILLY & CO.	SSB	BAQSIMI (NASAL)
DIAZOXIDE 50 MG/ML ORAL SUSP	generic	GEN	DIAZOXIDE SUSPENSION (ORAL)
GLUCAGEN 1 MG HYPOKIT	NOVO NORDISK	GEN	GLUCAGON (INJECTION)
GLUCAGON 1 MG EMERGENCY KIT	FRESENIUS KABI	SSB	GLUCAGON EMERGENCY KIT (FRESENIUS) (INJECTION)
GLUCAGON 1 MG VIAL	generic	GEN	GLUCAGON EMERGENCY KIT (FRESENIUS) (INJECTION)
GLUCAGON 1 MG EMERGENCY KIT	generic	GEN	GLUCAGON EMERGENCY KIT (INJECTION)
GLUCAGON 1 MG VIAL	generic	GEN	GLUCAGON EMERGENCY KIT (INJECTION)
GVOKE HYPOPEN 1PK 0.5MG/0.1 ML	XERIS PHARMACEU	SSB	GVOKE PEN (SUBCUTANEOUS)
GVOKE HYPOPEN 1-PK 1 MG/0.2 ML	XERIS PHARMACEU	SSB	GVOKE PEN (SUBCUTANEOUS)
GVOKE HYPOPEN 2PK 0.5MG/0.1 ML	XERIS PHARMACEU	SSB	GVOKE PEN (SUBCUTANEOUS)
GVOKE HYPOPEN 2-PK 1 MG/0.2 ML	XERIS PHARMACEU	SSB	GVOKE PEN (SUBCUTANEOUS)
GVOKE PFS 1PK 0.5MG/0.1 ML SYR	XERIS PHARMACEU	SSB	GVOKE SYRINGE (SUBCUTANEOUS)
GVOKE PFS 1-PK 1 MG/0.2 ML SYR	XERIS PHARMACEU	SSB	GVOKE SYRINGE (SUBCUTANEOUS)
GVOKE PFS 2PK 0.5MG/0.1 ML SYR	XERIS PHARMACEU	SSB	GVOKE SYRINGE (SUBCUTANEOUS)
GVOKE PFS 2-PK 1 MG/0.2 ML SYR	XERIS PHARMACEU	SSB	GVOKE SYRINGE (SUBCUTANEOUS)
GVOKE 1 MG/0.2 ML KIT	XERIS PHARMACEU	SSB	GVOKE VIAL (SUBCUTANEOUS)
GVOKE 1 MG/0.2 ML VIAL	XERIS PHARMACEU	SSB	GVOKE VIAL (SUBCUTANEOUS)
PROGLYCEM 50 MG/ML ORAL SUSP	TEVA SPECIALTY	SSB	PROGLYCEM SUSPENSION (ORAL)
ZEGALOGUE 0.6 MG/0.6ML AUTOINJ	ZEALAND PH/NOVO	SSB	ZEGALOGUE AUTOINJECTOR (SUBCUTANEOUS)
ZEGALOGUE 0.6 MG/0.6 ML SYRING	ZEALAND PH/NOVO	SSB	ZEGALOGUE SYRINGE (SUBCUTANEOUS)

Glucagon (Baqsimi®) Abbreviated New Drug Update (ANDU)

February 2022

OVERVIEW[1]

- Indication
  - An antihypoglycemic agent indicated for the treatment of severe hypoglycemia in patients with diabetes ages ≥ 4 years
- Contraindications/Warnings
  - Contraindications: pheochromocytoma, insulinoma, known hypersensitivity to glucagon or to any of the excipients
  - Warnings
    - Administration may stimulate catecholamine release in patients with pheochromocytoma resulting in a substantial increase in blood pressure
    - Patients with insulinoma may experience a lack of efficacy due to exaggerated insulin release after administration and hypoglycemia can result
    - Hypersensitivity and allergic reactions have been reported including generalized rash, hypotension, and anaphylactic shock with breathing difficulties
    - Lack of efficacy in patients with decreased hepatic glycogen (e.g., starvation, adrenal insufficiency, chronic hypoglycemia); these patients should be treated with glucose
- Drug Interactions
  - Patients taking beta-blockers may experience a transient increase in blood pressure and pulse.
  - Patients taking indomethacin may not experience an increase in blood sugar after glucagon administration and could potentially experience hypoglycemia.
  - Concomitant use with warfarin may increase the anticoagulant effect of the drug.
  - A common cold with decongestant use or with nasal congestion did not impact the pharmacodynamics of intranasal glucagon.
- Common Adverse Effects
  - The most common adverse reactions, occurring in ≥ 10% of adults and pediatric patients, respectively, in clinical trials were nausea (26.1%; 16.7%), vomiting (15%; 30.6%), headache (18.3%; 25%), upper respiratory tract irritation (e.g., rhinorrhea, nasal discomfort, nasal congestion, cough, epistaxis [12.4%; 16.7%]), watery eyes (58.8%; 47.2%), redness of eyes (24.8%; 13.9%), itchy nose (39.2%; 27.8%), itchy throat (12.4%; 2.8%), itchy eyes (21.6%; 16.7%), and sneezing (19.6%; 19.4%).
  - While treatment-emergent anti-drug antibodies were detected in a small number of patients (2%; 3 out of 124 patients) treated with glucagon intranasal, no neutralizing antibodies were detected.

- Special Populations
  - Pregnancy – Limited data (case reports, observational studies) with glucagon use in pregnant women have not found a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.
  - Pediatric Use – Safety and efficacy have been established for pediatric patients ≥ 4 years.
  - Geriatric Use – Clinical trials did not include an adequate number of patients ≥ 65 years of age to determine whether efficacy and safety differ from use in younger subjects.
- Availability – Single-dose intranasal device containing 3 mg of glucagon powder; store product at temperatures up to 30°C in the shrink wrapped tube provided until time of use; if the tube has been opened, product may have been exposed to moisture and may not work as intended
- Dosage – Insert the tip of device into 1 nostril and press the device plunger all the way in (until the green line is no longer visible). The dose does not require inhalation. Contact emergency assistance immediately after administering the dose. If no response after 15 minutes, an additional 3 mg dose from a new device may be administered while awaiting emergency assistance.
- Clinical Trials[2]
  - Study 1 was a randomized, multicenter, open-label, 2-period, crossover study that included a total of 70 adults with type 1 diabetes and compared a 3 mg intranasal dose of glucagon to a 1 mg dose of intramuscular glucagon (IMG).[3] Insulin was used to decrease the blood glucose (BG) level to < 60 mg/dL. Glucose nadir was defined as the minimum BG measurement at the time of (or within 10 minutes) following glucose administration. The primary outcome measure was the proportion of patients that achieved an increase in BG ≥ 70 mg/dL or an increase of ≥ 20 mg/dL from glucose nadir within 30 minutes after receiving glucagon (without receiving additional action to raise BG levels). The study drug demonstrated non-inferiority to IMG in reversing insulin-induced hypoglycemia with 100% of treated patients in both groups achieving the primary outcome measure.
  - Study 2 was a randomized, multicenter, open-label, 2-period, crossover study that included a total of 83 adults with type 1 (n=77) and type 2 (n=6) diabetes and compared a 3 mg dose of intranasal glucagon to a 1 mg dose of IMG.[4] Insulin was used to decrease the BG level to a target of < 50 mg/dL. Glucose nadir was defined as the minimum BG measurement at the time of (or within 10 minutes) following glucose administration. The primary outcome measure was the proportion of patients that achieved an increase in BG ≥ 70 mg/dL or an increase of ≥ 20 mg/dL from glucose nadir within 30 minutes after receiving glucagon (without receiving additional action to raise BG levels). The study drug demonstrated non-inferiority to IMG in reversing insulin-induced hypoglycemia in 98.8% (79 out of 80 patients) compared to 100% of those treated with IMG.
  - Study 3 was a randomized, multicenter trial that included a total of 48 pediatric patients ages 4 years to < 17 years old with type 1 diabetes and compared a 3 mg dose of intranasal glucagon to a 1 mg dose of IMG.[5] Insulin was used to decrease the BG level to < 80 mg/dL. Glucose nadir was defined as the minimum BG measurement at the time of (or within 10 minutes) following glucose administration. The primary outcome measure was the proportion of patients that achieved an increase of ≥ 20 mg/dL from glucose nadir within 30 minutes after receiving glucagon (without receiving additional action to raise BG levels). The study drug demonstrated

non-inferiority to IMG in reversing insulin-induced hypoglycemia with 100% of treated patients in both groups achieving the primary outcome measure.

CLINICAL CONSIDERATIONS[6,7]

- Hypoglycemia is classified as level 1 (glucose < 70 mg/dL and ≥ 54 mg/dL), level 2 (glucose < 54 mg/dL), and level 3 (severe event: altered mental and/or physical status requiring assistance to treat). It can be reversed through administration of rapid-acting glucose or glucagon. For patients unable or not willing to consume carbohydrates by mouth, use of glucagon is indicated for treating hypoglycemia. The ADA guidelines acknowledge that intranasal glucagon and ready-to-inject glucagon preparations for subcutaneous injection are available, in addition to traditional glucagon injection powder requiring reconstitution. No specific glucagon product is identified as being preferred.
  - The American Diabetes Association (ADA) 2022 Standards of Medical Care in Diabetes recommends glucagon should be prescribed for all individuals who are at an increased risk for level 2 hypoglycemia (blood glucose < 54 mg/dL) or level 3 hypoglycemia, to have accessible for use, as needed. Caregivers, school personnel, or family members of these individuals should know where it is as well as when and how to administer it; glucagon administration is not limited to healthcare providers (level of evidence, E [expert consensus or clinical experience]).
- Glucagon nasal powder (Baqsimi) is a portable, dry nasal spray form of glucagon available in a single, fixed-dose intranasal device that does not require reconstitution or inhalation. Glucagon nasal powder was the first ready-to-use glucagon product and received approval in July 2019. Glucagon injection (Gvoke®) represents the second ready-to-use glucagon product to be approved by the FDA and the first FDA-approved ready-to-use *injectable* glucagon product; it was approved in September 2019. Dasiglucagon (Zegalogue®) is the third ready-to-use glucagon product and second ready-to-use *injectable* product to receive FDA approval; it received FDA approval in March 2021.[8]
- Prior to the approval of these products, glucagon was only available as a powder that required reconstitution to be administered; these new drugs were developed to increase the ease of administration by patients and caregivers.
- When compared to intramuscular glucagon, intranasal glucagon demonstrated non-inferiority and was able to reverse insulin-induced hypoglycemia. Furthermore, intranasal glucagon (Baqsimi) may be considered a viable, injection-free hypoglycemia rescue agent for type 1 and type 2 diabetics ages ≥ 4 years. Eli Lilly, who also manufactures an injectable glucagon kit, has launched the intranasal glucagon (Baqsimi).

SUGGESTED UTILIZATION MANAGEMENT

Anticipated Therapeutic Class Review (TCR) Placement	N/A
Clinical Edit	**Initial Approval Criteria** ▪ Patient is ≥ 4 years of age; **AND** ▪ Patient has a diagnosis of type 1 or type 2 diabetes; **AND** ▪ Patients does NOT have pheochromocytoma, an insulinoma, or known hypersensitivity to glucagon or any of the excipients in the product. **Renewal Criteria** ▪ Patient must continue to meet initial criteria.
Quantity Limit	None
Duration of Approval	1 year (initial and renewal)
Drug to Disease Hard Edit	Pheochromocytoma, insulinoma

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8 Zegalogue [package insert]. Durham, NC; Zealand; March 2021

Glucagon injection (Gvoke®) Abbreviated New Drug Update (ANDU)

February 2022

OVERVIEW[1]

- Indication
  - An antihypoglycemic agent indicated for the treatment of severe hypoglycemia in patients with diabetes ages ≥ 2 years
- Contraindications/Warnings
  - Contraindications: pheochromocytoma, insulinoma, known hypersensitivity to glucagon or to any of the excipients
  - Warnings
    - Administration may stimulate catecholamine release in patients with pheochromocytoma
    - Patients with insulinoma may experience a lack of efficacy due to exaggerated insulin release after administration
    - Hypersensitivity and allergic reactions have been reported including generalized rash, hypotension, and anaphylactic shock with breathing difficulties
    - Lack of efficacy in patients with decreased hepatic glycogen; these patients should be treated with glucose
    - Post marketing reports of a skin rash known as Necrolytic Migratory Erythema (NME) has been reported following continuous glucagon infusion and resolved upon discontinuation
- Drug Interactions
  - Patients taking beta-blockers may experience a transient increase in blood pressure and pulse.
  - Patients taking indomethacin may not experience an increase in blood sugar after administration and could potentially experience hypoglycemia.
  - Concomitant use with warfarin may increase the anticoagulant effect of the drug.
- Common Adverse Effects
  - The most common adverse reactions occurring in ≥ 2% of adults and pediatric patients in clinical trials were nausea (30%; 45%), vomiting (16%; 19%), headache (5%; 7%), and injection site reaction (7%; 3%).

Magellan Rx MANAGEMENT℠

- Special Populations
  - Pregnancy – Limited data (case reports, observational studies) with glucagon use in pregnant women have not found a drug-associated risk for major birth defects, miscarriage, or adverse maternal or fetal outcomes.
  - Pediatrics – Safety and efficacy have been established for pediatric patients ≥ 2 years. Safety and efficacy have not been established for patients younger than 2 years of age.
  - Geriatrics – Clinical trials did not include an adequate number of patients ≥ 65 years of age to determine whether efficacy and safety are different in these patients compared to younger subjects.
- Availability
  - 0.5 mg/0.1 mL and a 1 mg/0.2 mL single-dose prefilled HypoPen autoinjector and single-dose prefilled syringes; HypoPen and prefilled syringe should be stored in the original sealed foil pouch until use
  - 1 mg/0.2 mL single-dose vial and syringe kit; the vial and pouched syringe should be stored together in the original carton until use
  - Store product at 20° to 25°C (excursions permitted between 15° to 30°C); do not store in the refrigerator or freezer or expose to extreme temperatures.
- Dosage
  - The dose is administered subcutaneously in the lower abdomen, outer thigh, or outer upper arm as directed by the Instructions for Use. The recommended dose for adults and pediatric patients age ≥ 12 years is 1 mg. The recommended dose is 0.5 mg for pediatric patients (≥ 2 years to < 12 years) weighing < 45 kg, and 1 mg for those who weigh ≥ 45 kg. Emergency assistance should be contacted immediately after administration. An additional dose from a new device should be given if after 15 minutes no response has occurred following the initial dose, while awaiting emergency assistance.
- Clinical Trials[2,3,4,5,6]
  - Study A and Study B were 2 randomized, controlled, blinded, multicenter, crossover, non-inferiority studies that included a total of 161 adults with type 1 diabetes mellitus (T1DM) aged 18 to 74 years of age (Study A, n=80, double-blinded; Study B, n=81, single-blinded) evaluating the efficacy of glucagon injection (autoinjector) compared to glucagon emergency kit (GEK). Both studies consisted of 2 office visits (7 to 28 days apart) where patients received an insulin infusion to induce hypoglycemia until a target plasma glucose of < 50 mg/dL was achieved. At that point, patients were randomized to receive a dose of glucagon 1 mg injection during 1 visit and GEK 1 mg at the other visit. Treatment success was defined as an increase in plasma glucose > 70 mg/dL or a relative increase of ≥ 20 mg/dL at 30 minutes after glucagon administration. In a pooled analysis of Study A and Study B, treatment success was achieved in 98.7% of glucagon injection versus 100% in the GEK group, and the comparison between groups met the pre-specified non-inferiority margin. The average time to achieve treatment success was 13.8 ±5.6 minutes in the glucagon injection group versus 10 ±3.6 minutes in the GEK group; this time was

not adjusted for the statistically significant shorter drug preparation and administration time for glucagon injection 27.3 (±19.7) seconds compared with 97.2 (±45.1) seconds in the GEK group (p<0.0001).

- Glucagon injection was also evaluated in a phase 3 sequential efficacy and safety study of 31 pediatric patients with T1DM. Patients received insulin to achieve a plasma glucose of < 80 mg/dL at which time they received a glucagon injection of either 0.5 mg (ages 2 to < 12 years) or 0.5 mg or 1 mg (ages ≥ 12 years). Patients were evaluated to determine if they achieved ≥ 25 mg/dL increase in blood glucose at 30 minutes post dose. All 30 patients (100%) who were able to be evaluated achieved the target blood glucose increase.

CLINICAL CONSIDERATIONS[7,8]

- Hypoglycemia is classified as level 1 (glucose < 70 mg/dL and ≥ 54 mg/dL), level 2 (glucose < 54 mg/dL), and level 3 (severe event: altered mental and/or physical status requiring assistance to treat). It can be reversed through administration of rapid-acting glucose or glucagon. For patients unable or not willing to consume carbohydrates by mouth, use of glucagon is indicated for treating hypoglycemia. The ADA guidelines acknowledge that intranasal glucagon and ready-to-inject glucagon preparations for subcutaneous injection are available, in addition to traditional glucagon injection powder requiring reconstitution. No specific glucagon product is identified as being preferred.
  - The American Diabetes Association (ADA) 2022 Standards of Medical Care in Diabetes recommends glucagon should be prescribed for all individuals who are at an increased risk for level 2 hypoglycemia (blood glucose < 54 mg/dL) or level 3 hypoglycemia, to have accessible for use, as needed. Caregivers, school personnel, or family members of these individuals should know where it is as well as when and how to administer it; glucagon administration is not limited to healthcare providers (level of evidence, E [expert consensus or clinical experience]).
- Glucagon injection (Gvoke) was the first FDA-approved ready-to-use *injectable* glucagon product.
- Glucagon injection (Gvoke) represents the second ready-to-use glucagon product to be approved by the FDA in 2019, after the intranasal glucagon (Baqsimi®) which was approved in July 2019.[9] Dasiglucagon (Zegalogue®) received FDA approval in March 2021 and is the third ready-to-use glucagon product and second ready-to-use *injectable* product to receive FDA approval; it is a glucagon analog, available as a 0.6 mg/0.6 mL single-dose autoinjector and single-dose prefilled syringe, indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged ≥ 6 years.[10]
- Prior to the approval of these products, glucagon was only available as a powder that required reconstitution to be administered; these drugs were developed to increase the ease of administration by patients and caregivers.
- Similar to another form of glucagon, glucagon injection (Gvoke) was able to reverse insulin-induced hypoglycemia, meeting the pre-specified non-inferiority margin. Glucagon injection (Gvoke) should be considered a viable rescue agent in severe hypoglycemia for patients with diabetes ages ≥ 2 years.

SUGGESTED UTILIZATION MANAGEMENT

Anticipated Therapeutic Class Review (TCR) Placement	N/A
Clinical Edit	**Initial Criteria** ▪ Patient is ≥ 2 years of age; **AND** ▪ Patient has a diagnosis of type 1 or type 2 diabetes; **AND** ▪ Patient does NOT have pheochromocytoma, an insulinoma, or known hypersensitivity to glucagon or any of the excipients in the product. **Renewal Criteria** ▪ Patient must continue to meet initial criteria.
Quantity Limit	None
Duration of Approval	1 year (initial and renewal
Drug to Disease Hard Edit	Pheochromocytoma, insulinoma

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10 Zegalogue [package insert]. Durham, NC; Zealand; March 2021

Dasiglucagon (Zegalogue®) Drug Bulletin

April 2022

Nonproprietary Name	dasiglucagon
Brand Name	Zegalogue
Manufacturer	Zealand
FDA Approval Date	March 22, 2021
Market Availability Date	June 2021[1]
Indication	Treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged ≥ 6 years old[2]
Dosage Form	0.6 mg/0.6 mL single-dose autoinjector and single-dose prefilled syringe
Dosage	0.6 mg via subcutaneous (SC) injection into the lower abdomen, buttocks, thigh, or outer upper arm; call for emergency assistance immediately after administering; if no response after 15 minutes, an additional 0.6 mg dose from a new device can be given; once responded to treatment, oral carbohydrates should be given

CLINICAL CONSIDERATIONS

- Dasiglucagon (Zegalogue) is a glucagon analog and a glucagon receptor agonist that acts as an antihypoglycemic agent to increase blood glucose levels through activation of the hepatic glucagon receptor.[3] This stimulates glycogen breakdown and release of glucose from the liver; as a result, hepatic reserves of glycogen are required for the antihypoglycemic effect.
- Safety [4] – substantial increase in blood pressure (BP) in patients with pheochromocytoma (contraindication and warning/precaution); hypoglycemia in those with insulinoma (contraindication and warning/precaution); other warnings/precautions include potential for hypersensitivity and allergic reactions and lack of effect in those with reduced hepatic glycogen; the most common adverse effects (≥ 2% of adults and pediatric patients) include nausea, vomiting, headache, and injection site pain; potential drug interactions include beta-blockers, indomethacin, and warfarin
- Efficacy – 3 randomized, double-blind, placebo-controlled, multicenter trials evaluated dasiglucagon in patients with type 1 diabetes with a controlled induction of hypoglycemia via intravenous (IV) insulin. Trial A and B enrolled adults and the blood glucose (BG) target during the induction period was < 60 mg/dL, whereas trial C enrolled pediatric patients 6 years to 17 years weighing ≥ 20 kg and targeted a hypoglycemia level of < 80 mg/dL. The primary endpoint for all 3 studies was time to BG recovery (increase in BG of ≥ 20 mg/dL from administration without additional intervention within 45 minutes [min]). There was a comparator arm in Trials A and C

with 1 mg glucagon for injection; however, there was not a formal hypothesis test for this comparison with dasiglucagon.[5]

- Trial A (NCT03378635; n=170) randomized patients 2:1:1 to dasiglucagon, placebo, and glucagon for injection and demonstrated the median time to BG recovery was significantly shorter for dasiglucagon compared to placebo (10 min; 95% confidence interval [CI], 10 to 10 versus 40 min; 95% CI, 30 to 40; $p < 0.001$). A similar time to BG recovery was found for dasiglucagon compared with glucagon for injection (10 min versus 12 min), respectively.
- Trial B (NCT03688711; n=45 patients) randomized patients 3:1 to dasiglucagon and placebo and demonstrated the median time to BG recovery was significantly shorter for dasiglucagon compared with placebo (10 min; 95% CI, 8 to 12 versus 35 min; 95% CI, 20 to -; $p < 0.001$).
- Trial C (NCT03667053; n=42 patients) randomized 2:1:1 to dasiglucagon, placebo, and glucagon for injection and demonstrated the median time to BG recovery was significantly shorter for dasiglucagon compared with placebo (10 min; 95% CI, 8 to 12 versus 30 min; 95% CI, 20 to -; $p < 0.001$). A similar time to BG recovery was found for dasiglucagon compared with glucagon for injection (10 min versus 10 min), respectively.

- Hypoglycemia is classified as level 1 (glucose < 70 mg/dL and ≥ 54 mg/dL), level 2 (glucose < 54 mg/dL), and level 3 (severe event: altered mental and/or physical status requiring assistance to treat). It can be reversed through administration of glucose- or carbohydrate-containing foods or glucagon. For patients unable or not willing to consume carbohydrates by mouth, use of glucagon is indicated for treating hypoglycemia. The American Diabetes Association (ADA) guidelines acknowledge that intranasal glucagon and ready-to-inject glucagon preparations for subcutaneous injection are available, in addition to traditional glucagon injection powder requiring reconstitution. No specific glucagon product is identified as being preferred.[6]
  - The ADA 2022 Standards of Medical Care in Diabetes recommends glucagon should be prescribed for all individuals who are at an increased risk for level 2 or level 3 hypoglycemia to have accessible for use, as needed. Caregivers, school personnel, or family members of these individuals should know where it is as well as when and how to administer it; glucagon administration is not limited to healthcare providers (level of evidence, E [expert consensus or clinical experience]).
- Dasiglucagon (Zegalogue) is the third ready-to-use glucagon product and second ready-to-use *injectable* product to receive FDA approval and is expected to compete with other ready-to-use glucagon products with similar indications. Prior to the approval of these products, glucagon was only available as a powder that required reconstitution to be administered; these drugs were developed to increase the ease of administration by patients and caregivers.
  - Intranasal glucagon (Baqsimi™) was approved in July 2019 as the first ready-to-use glucagon product and is FDA-approved for the treatment of severe hypoglycemia in patients with diabetes ages ≥ 4 years.[7]

- Glucagon injection (Gvoke®) was the second ready-to-use glucagon product to be approved by the FDA (September 2019) and the first FDA-approved ready-to-use *injectable* glucagon product. It is indicated for the treatment of severe hypoglycemia in patients with diabetes ages ≥ 2 years. Gvoke is also available in a single-dose prefilled syringe and auto-injector (0.5 mg/0.1 mL and 1 mg/0.2 mL strengths) as well as a single-dose vial and syringe kit (1 mg/0.2 mL strength) for administration into the lower abdomen, outer thigh, or outer upper arm. [8]

SUGGESTED UTILIZATION MANAGEMENT

Anticipated Therapeutic Class Review (TCR) Placement	N/A
Clinical Edit	**Initial Criteria** ▪ Patient is ≥ 6 years of age; **AND** ▪ Patient has a diagnosis of type 1 or type 2 diabetes; **AND** ▪ Patient does NOT have a pheochromocytoma or an insulinoma. **Renewal Criteria** ▪ Patient must continue to meet initial criteria.
Quantity Limit	None
Duration of Approval	1 year (initial and renewal)
Drug to Disease Hard Edit	Pheochromocytoma, insulinoma

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