Zegalogue® (dasiglucagon)

Policy # 00764
Original Effective Date: 12/13/2021
Current Effective Date: 12/13/2021

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Zegalogue®‡ (dasiglucagon) to be **eligible for coverage*** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Zegalogue (dasiglucagon) will be considered when the following criteria are met:

- Patient has a diagnosis of diabetes; AND
- Patient is 6 years of age or older; AND
- Requested medication is being used for the treatment of severe hypoglycemia; AND
- Patient has tried and failed (e.g., intolerance or inadequate response) TWO of the following glucagon agents: Glucagon Emergency Kit®‡ (brand or generic), Glucagen Hypokit®‡, Gvoke®‡, or Baqsimi™‡ unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Zegalogue (dasiglucagon) when the patient has not tried and failed TWO of the following glucagon agents: Glucagon Emergency Kit (brand or generic), Glucagen Hypokit, Gvoke, or Baqsimi to be **not medically necessary.****

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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Zegalogue (dasiglucagon) when the patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Zegalogue is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above. This product is a glucagon receptor agonist, much like the existing products on the market today. However, Zegalogue is an analog of glucagon while the other products' active ingredient is glucagon. This agonist action increases the blood glucose concentration by stimulating glycogen breakdown and the release of glucose from the liver. Zegalogue is available as an autoinjector and a prefilled syringe for subcutaneous injection. Zegalogue may be stored refrigerated until expiration or at room temperature for 12 months or 36 months refrigerated. Other glucagon formulations may be stored up to 24 months. The dose in adult and pediatric patients is 0.6 mg. If there has been no response after 15 minutes, an additional dose of Zegalogue from a new device may be administered.

Other options exist in this class. Products include Glucagon Emergency Kit (brand or generic), Glucagen Hypokit, Gvoke, or Baqsimi. Glucagon Emergency Kit and Glucagen Hypokit require a multi-step reconstitution process. Gvoke is available in a ready to use autoinjector and prefilled syringe form, similar to Zegalogue, but is indicated down to 2 years of age, where Zegalogue is only approved down to 6 years of age. Baqsimi is a ready to use option that is administered intranasally and is indicated down to 4 years of age. There are no direct comparisons of Zegalogue to the newer ready to use products (Gvoke, Baqsimi) so no claims of superiority can be made. In Zegalogue's clinical trials, it was compared statistically to placebo, and of course performed better than placebo. However, it did perform similarly to the reference product in the trial, Glucagen Hypokit. Zegalogue is simply another option in this class of medications where a multitude of other options exist.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Zegalogue is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above.

Rationale/Source

The purpose of this policy is to ensure that Zegalogue is being used according to its FDA approved indication as well as to ensure that equally efficacious preferred formulary options are used prior to Zegalogue. Options for use include similar ready to use formulations of glucagon as well as options for reconstitution prior to use.

References

1. Zegalogue [package insert]. Zealand Pharma. Denmark. Updated April 2021.
2. Zegalogue Drug Evaluation. Express Scripts.
3. Gvoke [package insert]. Xeris Pharmaceuticals. Chicago, Illinois. Updated August 2021.
4. Baqsimi [package insert]. Eli Lilly. Indianapolis, Indiana. Updated August 2021.
5. Glucagen Hypokit [package insert]. Novo Nordisk. Denmark. Updated March 2021.
6. Glucagon Emergency Kit [package insert]. Eli Lilly. Indianapolis, Indiana. Updated July 2018.

Policy History

Original Effective Date: 12/13/2021
Current Effective Date: 12/13/2021
11/04/2021 Medical Policy Committee review
11/10/2021 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 11/2022

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.