3-Minute Verbal State Medicaid Template ZEGALOGUE® (dasiglucagon) injection



My name is Emily Smith, and I am the US West HEOR Director with Zealand Pharma. Thank you for this opportunity to provide requested information in support of adding ZEGALOGUE® (dasiglucagon) injection, as unrestricted to the Nevada Medicaid preferred drug list.

ZEGALOGUE is indicated for the treatment of severe hypoglycemia in pediatric and adult patients with diabetes aged 6 years and above. I refer you to the full ZEGALOGUE prescribing information for complete warnings, precautions and adverse reactions that can be found at Zegalogue.com (https://www.zegalogue.com/).¹

ZEGALOGUE is a first-in-class glucagon analog, with improved aqueous solubility compared to native human glucagon and is available as an autoinjector or prefilled syringe that does not require reconstitution prior to administration.¹ ZEGALOGUE has a 3-year expiration from the date of manufacture and may be stored in refrigeration for this duration.² Once removed from refrigeration, ZEGALOGUE may be stored at room temperature for 12 months unless it expires before then.²

In each of the three pivotal Phase 3 trials (2 adult and 1 pediatric), the primary endpoint was time to plasma glucose recovery, defined as an increase in blood glucose of ≥20 mg/dL from time of administration.¹ ZEGALOGUE met all primary and secondary endpoints and demonstrated a median time to plasma glucose recovery of 10 minutes in adult and pediatric subjects.³,4,5 Within the first 15 minutes post-dose, up to 99% of adults and 95% of pediatrics obtained plasma glucose recovery.¹ Adverse events were similar in occurrence and frequency to other injectable glucagon products, including nausea, vomiting, headache, diarrhea (adults only) and injection site pain.³,4,5

Budget impact modeling demonstrated that ZEGALOGUE may have a favorable budget impact for U.S. payers due to its rate of successful administration and percentage of patients achieving recovery.⁶ In a population of 1M hypothetical covered lives, with an occurrence of 12,006 severe hypoglycemic events per year, treatment with ZEGALOGUE was estimated to provide a total cost savings of 62% compared to glucagon rescue products that require multiple steps for reconstitution prior to injection.^{6,7,8} Reconstitution of glucagon rescue kits result in a 34% probability of successful initial full dose administration.^{9,10} Treatment with ZEGALOGUE was estimated to provide a total cost savings of 20% when compared to Gvoke[®].⁶ Results from pivotal phase 3 trials, showed Gvokehad a mean time to plasma glucose recovery of 13.8 minutes, with only 78.9% of adult patients achieving recovery in the first 15 minutes after injection.^{11,12}

In conclusion, ZEGALOGUE demonstrated a time to plasma glucose recovery of 10 minutes with up to 99% of adults³ and 95% of pediatrics⁵ rescued within 15 minutes. I respectfully request that ZEGALOGUE be added to the Preferred Drug List (or PDL) unrestricted for the Medicaid beneficiaries of Nevada. Thank you for the opportunity to share this information with you today and I will be happy to answer any questions.

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REFERENCES

- 1. Zealand Pharma. Zegalogue® Prescribing Information, 04/2021.
- 2. Zealand Pharma. Zeagalogue® A/S NDA Approval Letter, 03/2021.
- 3. Pieber TR, Aronson R, Hövelmann U, et al. Dasiglucagon: a next-generation glucagon analog for rapid and effective treatment of severe hypoglycemia results of phase 3 randomized double-blind clinical trial. *Diabetes Care* 2021;44:1–7. doi.10.2337/DC20-2995.
- 4. Bailey TS, Willard J, Klaff LJ, et al. Dasiglucagon, a next generation glucagon analogue, for treatment of severe hypoglycemis via an autoinjector device: Results of a phase 2, randomized, double-blind trial. *Diabetes Obes Metab*. 2021; 1-7. doi.org/10.1111/dom.14475.
- 5. Battelino T, Tehranchi R, Bailey T, et al. Dasiglucagon, a next-generation ready-to-use glucagon analog, for treatment of severe hypoglycemia in children and adolescents with type 1 diabetes: Results of a phase 3, randomized controlled trial. *Pediatr Diabetes*. 2021;22(5): 734–741. doi.org/10.1111/pedi.13220.
- 6. Zealand Pharma. Zegalogue® Budget Impact Model. Data on file.
- 7. Eli Lilly. Glucagon Emergency Kit Prescribing Information, 06/2018.
- 8. Novo Nordisk A/S. GlucaGen Hypokit Prescribing Information, 06/2020.
- 9. Bailey NC, Dimsits J, Tehranchi R, Kendall DM, Bailey TS. Dasiglucagon ready-to-use autoinjector is more reliably and quickly administered than glucagon emergency kit (GEK). *Diabetes*. 2021;70 (Suppl.) doi.org/10.2337/db21-137-0.
- 10. Yale JF, Dulude H, Egeth M, et al. Faster use and fewer failures with needle-free nasal glucagon versus injectable glucagon in severe hypoglycemia rescue: a simulation study. *Diabetes Technol Ther*. 2017;19(7):423-432. doi:10.1089/dia.2016.0460.
- 11. Xeris Pharmaceuticals. Gvoke® Prescribing Information, 09/2019.
- 12. Gvoke® FDA submission 2017, CDER Clinical Review Template 2. Version date: September 6, 2017 for all NDAs and BLAs.