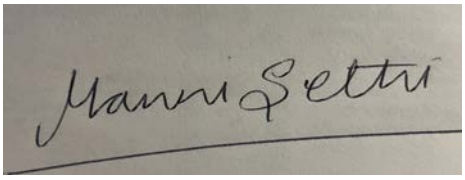
Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community Health Choices	**Submission Date**:1/25/2023
Policy Number: CCP.1440	**Effective Date:** 2/2020 **Revision Date:** January 1, 2023
Policy Name: V-Go® disposable insulin pump	
Type of Submission – Check all that apply: ☐ **New Policy** **X Revised Policy*** ☐ **Annual Review – No Revisions** ☐ **Statewide PDL**	
***All revisions to the policy must be highlighted using track changes throughout the document.** **Please provide any clarifying information for the policy below:** Please see tracked changes for updates	
Name of Authorized Individual (Please type or print): Manni Sethi, MD	**Signature of Authorized Individual:** 

V-Go® disposable insulin pump

Clinical Policy ID: CCP.1440

Recent review date: 1/2023

Next review date: 5/2024

Policy contains: Disposable; nonprogrammable; insulin pump; continuous subcutaneous insulin infusion.

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

The V-Go® Disposable Insulin Delivery Device (Valeritas Inc., Shrewsbury, Massachusetts) is investigational/not clinically proven and, therefore, not medically necessary.

For any determinations of medical necessity for medications, refer to the applicable state approved pharmacy policy.

Limitations
Not applicable.

Alternative covered services

- Diabetes education and counseling.
- Multiple daily injections of insulin.
- Non-disposable, programmable continuous subcutaneous insulin infusion pump.
- Non-insulin glucose lowering medications.

Background

Diabetes is usually diagnosed according to one of the following criteria (American Diabetes Association, 2019):

- Fasting plasma glucose ≥ 126 mg/dL (7.0 mmol/L).
- Two-hour plasma glucose ≥ 200 mg/dL (11.1 mmol/L) after a 75-gram oral glucose tolerance test.
- A1c ≥ 6.5% (48 mmol/mol).

- Random plasma glucose ≥ 200 mg/dL (11.1 mmol/L) in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

Intensive insulin therapy is an aggressive treatment approach for persons with diabetes who require close monitoring of blood glucose levels and frequent doses of insulin. Innovations in insulin delivery and glucose monitoring are designed to improve glycemic control and quality of life while limiting adverse effects, such as hypoglycemia and weight gain.

Insulin pump therapy is an alternative to insulin injections by syringes or insulin pens. Insulin pumps are connected to the body via an infusion set and tubing for delivering rapid- or short-acting insulin via subcutaneous routes, or they may be implanted using intraperitoneal routes. They may be integrated with real-time continuous glucose monitoring sensors (sensor-augmented pumps). Insulin doses may be delivered as:

- Basal rates delivered continuously over 24 hours.
- Bolus doses to cover carbohydrates in meals.
- Corrective or supplemental doses.

Many persons with diabetes continue to experience considerable fear of hypoglycemia, which may compromise care and treatment adherence, leading to worsening metabolic control (Lin, 2020). With insulin pumps, the tubing can kink or disconnect and compromise convenient and discreet use. As a result, a number of external insulin infusion patch pumps have been developed that involve no visible tubing, adhere to the body, are partially or completely disposable, and may be worn and operated discreetly under clothing, while glucose levels are continuously monitored. Some require a separate wireless controller device for programming, and others are preprogrammed with all necessary control components (Lin, 2020).

Hormones such as insulin are regulated as drugs under the Federal Food, Drug and Cosmetic Act (21CFR201). More than 70 insulin pumps have received U.S. Food and Drug Administration (2022) 510(k) premarket approval as Class II devices. Each must comply with federal law for labeling (U.S. Food and Drug Administration, 2022).

The V-Go is a fully disposable, nonprogrammable, single-use insulin infusion device with an integrated subcutaneous needle indicated for adult patients requiring insulin, and is approved for use by the U.S. Food and Drug Administration (2011). It is approved for U-100 fast-acting insulins (Valeritas, 2021). Three device models (delivering 20, 30, or 40 units/day) provide a continuous preset basal rate of insulin, allow for on-demand bolus dosing around mealtimes, and must be replaced daily.

Boluses are given by pressing one or two buttons to deliver a fixed amount, usually two units of insulin. Although the amount of remaining insulin is visible, the device cannot track how much insulin has been taken. As it has no remote controller, a change in bolus rate requires a change in model. The manufacturer's website notes that if regular adjustments or modifications to the preset basal rate of insulin are required in a 24-hour period, or if the amount of insulin used at meals requires adjustments of less than 2-unit increments, use of the V-Go may result in hypoglycemia (Valeritas, 2021).

Findings

We included seven studies in the policy (Everitt, 2019; Johns, 2014; Lajara, 2016; Ravel, 2019; Rosenfeld, 2012; Sutton, 2018; Winter, 2015). The evidence supporting the clinical utility of the V-Go insulin pump consists of retrospective analyses that enrolled non-pregnant adults with poorly controlled Type 2 diabetes on insulin

therapy and non-insulin glucose lowering medications. All but Rosenfeld (2012) and Winter (2015) were funded by the manufacturer, with a high likelihood of overlapping study populations.

An Endocrine Society guideline recommends continuous subcutaneous insulin infusion therapy for diabetes-educated people with insulinopenic Type 2 diabetes who have poor glycemic control despite intensive insulin therapy, oral agents, other injectable therapy, and lifestyle modifications (Peters, 2016). Mental and psychological status, prior adherence with diabetes self-care measures, willingness and interest in trying the device, and compliance with the required follow-up visits are important considerations.

Results of early preliminary analyses (Johns, 2014; Rosenfeld, 2012; Winter, 2015) suggest V-Go may improve glycemic control, reduce costs of diabetes care in the short term, and increase patient acceptance and satisfaction compared to prior insulin delivery options. Results of subsequently published retrospective studies with follow-up durations of up to 14 months (Everitt, 2019; Lajara, 2016; Ravel, 2019; Sutton, 2018) confirm sustained significant reductions in A1c targets, total daily dose of insulin, and related costs.

The limitations of the evidence reflect their retrospective design. They include small numbers of participants, lack of an independent control group, and inadequate description of enrollment criteria or baseline characteristics that prevent determination of the optimal candidate for the device. Although retrospective analyses may reflect real-world clinical practice, there is risk of selection bias, and potential confounders such as use of other glucose-lowering agents, insulin adherence, and diet adherence may not be accounted for in the analyses. Systematic collection of adverse events was not consistently reported, nor were reasons for discontinuing V-Go.

In 2019, more than 500 device events were reported to the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience database (U.S. Food and Drug Administration, 2019), similar to data reported in prior years. Most incidents were of device malfunction, although data of impact on patient outcome were not always reported.

Device limitations and current evidence suggest the best candidates for V-Go are patients with Type 2 diabetes on simple insulin regimens (Ginsberg, 2019). They may require basal-bolus therapy but would not be using multiple basal insulin rates and would not need an additional insulin push for the dawn phenomenon. However, prospective studies that address the shortcomings in the evidence are needed first to determine relative safety, effectiveness, and optimal candidacy.

In 2021, we updated the references (American Diabetes Association, 2019; Grunberger, 2020) and made no policy changes.

In 2022, we added several recent reviews, including:

- Diabetes patients (n = 136) using the V-Go device showed effectiveness and safety using either human regular insulin or rapid acting insulin; cost savings using human regular insulin are large (Mora, 2020). However, a study of 14,238 Swedish diabetes patients found higher average annual cost of those using insulin pumps versus those with multiple daily injections ($12,928 and $9,005) (Grip, 2021).
- Diabetes patients (n = 139) switching to V-Go significantly reduced A1C, using significantly less insulin (total daily dose), especially those prescribed a basal-bolus regimen (Zeidan, 2020).
- After switching to V-Go, 283 type 2 diabetes patients with suboptimal control had significantly lower A1C and total daily dose after seven months; those considered high risk fell from 46% to 24% (Hundal, 2020).

In 2023, we added a review (n = 44) that found use of V-Go significantly reduced A1C and daily insulin requirements with no impact on weight or body mass index (Meade, 2021).

References

On October 27, 2022, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “Insulin Infusion Systems” (MeSH) and the free text term “V-Go.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

American Diabetes Association. Standards of medical care in diabetes — 2020. *Diabetes Care.* January 01 2020;43: Suppl. 1. https://care.diabetesjournals.org/content/43/Supplement_1. Published 2019. Doi: 10.2337/dc20-Sint.

Everitt B, Harrison HC, Jr., Nikkel C, Laswell E, Chen AMH. Clinical and economic considerations based on persistency with a novel insulin delivery device versus conventional insulin delivery in patients with type 2 diabetes: A retrospective analysis. *Res Social Adm Pharm.* 2019;15(9):1126-1132. Doi: 10.1016/j.sapharm.2018.09.016.

Ginsberg BH. Patch pumps for insulin. *J Diabetes Sci Technol.* 2019;13(1):27-33. Doi: 10.1177/1932296818786513.

Grip ET, Svensson A-M, Miftarai M, et al. Real-world costs of continuous insulin pump therapy and multiple daily injections for type 1 diabetes: A population-based and propensity-matched cohort from the Swedish National Diabetes Register. *Diabetes Care*. 2019;42(4):545-552. Doi: 10.2337/dc18-1850.

Grunberger G, Rosenfeld CR, Bode BW, et al. Effectiveness of V-Go® for patients with type 2 diabetes in a real-world setting: A prospective observational study. *Drugs Real World Outcomes*. 2020;7(1):31-40. Doi: 10.1007/s40801-019-00173-8.

Hundal R, Kowalyk S, Wakim A, Nikkel C, Ii JHS, Doyle M. Multicenter real-world assessment of the effectiveness of V-Go wearable insulin delivery device in adult patients with type 2 diabetes (ENABLE Study): A retrospective analysis. *Med Devices (Auckl)*. 2020;13:283-291. Doi: 10.2147/MDER.S265869.

Johns BR, Jones TC, Sink JH, 2nd, Cooke CE. Real-world assessment of glycemic control after V-Go® initiation in an endocrine practice in the southeastern United States. *J Diabetes Sci Technol.* 2014;8(5):1060-1061. Doi: 10.1177/1932296814537041.

Lajara R, Nikkel C, Abbott S. The clinical and economic impact of the V-Go® disposable insulin delivery device for insulin delivery in patients with poorly controlled diabetes at high risk. *Drugs Real World Outcomes.* 2016;3(2):191-199. Doi: 10.1007/s40801-016-0075-4.

Lin YK, Fisher SJ, Pop-Busui R. Hypoglycemia unawareness and autonomic dysfunction in diabetes: Lessons learned and roles of diabetes technologies. *J Diabetes Investig*. 2020;11(6):1388-1402. Doi: 10.1111/jdi.13290.

Meade LM, Battise D. Evaluation of clinical outcomes with the V-Go wearable insulin delivery device in patients with type 2 diabetes. *Clin Diabetes*. 2021;39(3):297-303. Doi: 10.2337/cd20-0094.

Mora PF, Sutton DR, Gore A, et al. Efficacy, safety and cost-effectiveness comparison between U-100 human regular insulin and rapid acting insulin when delivered by V-Go wearable insulin delivery device in type 2 diabetes. *BMJ Open Diabetes Res Care*. 2020;8(2):e001832. Doi: 10.1136/bmjdrc-2020-001832.

Peters AL, Ahmann AJ, Battelino T, et al. Diabetes technology-continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2016;101(11):3922-3937. Doi: 10.1210/jc.2016-2534.

Raval AD, Nguyen MH, Zhou S, et al. Effect of V-Go versus multiple daily injections on glycemic control, insulin use, and diabetes medication costs among individuals with type 2 diabetes mellitus. *J Manag Care Spec Pharm.* 2019;25(10):1111-1123. Doi: 10.18553/jmcp.2019.25.10.1111.

Rosenfeld CR, Bohannon NJ, Bode B, et al. The V-Go insulin delivery device used in clinical practice: Patient perception and retrospective analysis of glycemic control. *Endocr Pract.* 2012;18(5):660-667. Doi: 10.4158/ep11362.or.

Sutton D, Higdon CD, Nikkel C, Hilsinger KA. Clinical benefits over time associated with use of V-Go wearable insulin delivery device in adult patients with diabetes: A retrospective analysis. *Adv Ther.* 2018;35(5):631-643. Doi: 10.1007/s12325-018-0703-3.

U.S. Food and Drug Administration. Letter to Valeritas, Inc. approving marketing. https://www.accessdata.fda.gov/cdrh_docs/pdf10/K103825.pdf. Published February 23, 2011.

U.S. Food and Drug Administration. Adverse Event Reporting Data Files. https://www.fda.gov/medical-devices/medical-device-reporting-mdr-how-report-medical-device-problems/adverse-event-reporting-data-files. Published June 21, 2019.

U.S. Food and Drug Administration. FDA 510(k) premarket notification database searched using product codes LZG. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Published October 24, 2022.

Valeritas Inc. The V-Go®. About V-Go. https://www.go-vgo.com/. Published 2022.

Winter A, Lintner M, Knezevich E. V-Go insulin delivery system versus multiple daily insulin injections for patients with uncontrolled type 2 diabetes mellitus. *J Diabetes Sci Technol.* 2015;9(5):1111-1116. Doi: 10.1177/1932296815580361.

Zeidan T, Nikkel C, Dziengelewski B, Wu S, Chen AMH. Clinical evaluation of Basal-Bolus therapy delivered by the V-Go wearable insulin delivery device in patients with type 2 diabetes: A retrospective analysis. *Pharmacy (Basel)*. 2020;8(4):215. Doi: 10.3390/pharmacy8040215.

Policy updates

12/2019: initial review date and clinical policy effective date: 2/2020

1/2021: Policy references updated.

1/2022: Policy references updated.

1/2023: Policy references updated.