MEDICAL MUTUAL®

Drug Policy

Policy:	V-Go device Disposable Insulin Delivery Device	Annual Review Date: 08/22/2024 Last Revised Date: 08/22/2024

OVERVIEW

Continuous insulin delivery may be required for type 1 diabetics or those type 2 diabetics who are insulin dependent. External insulin pumps deliver insulin through a catheter and needle into fatty skin tissue. The V-Go device received approval in 2010 from the Food and Drug Administration (FDA). The V-Go device is filled with insulin by the patient and adheres to the skin via a patch. A needle delivers the insulin and the device is removed every twenty-four hours. It is approved on the basis that the device is substantially equivalent to legally marketed predicate devices. In applications to the FDA, only Novolog and Humalog have been referenced as insulin used in the V-Go device.

POLICY STATEMENT

This policy involves the use of V-Go device. Prior authorization is recommended for pharmacy benefit coverage of V-Go device. Not all plans cover insulin delivery devices via their prescription coverage. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of V-Go device is recommended in those who meet the following criteria:

Initial Therapy. Members must meet ALL of the following criteria:

A. The patient is 18 years of age or older; AND
B. The patient requires continuous subcutaneous infusion of either 20 Units, 30 Units, or 40 Units of basal insulin in a 24-hour time period and on-demand dosing of up to 36 Units of bolus insulin in a 24-hour time period; AND
C. The patient must be using a rapid-acting insulin product (U-100 only) in the device; AND
D. The patient has been using multiple doses of insulin injections a day (3 injections daily or more); AND
E. The patient has worked with a provider to adjust dose of insulin for at least 6 months and failed to meet glucose goals; AND
F. The patient does not need to make regular adjustments or modifications to their basal rate during a 24-hour period, or patient's amount of bolus insulin used does not require adjustments of less than 2 unit increments; AND
G. The patient meets one of the following (i, ii, iii, iv OR v) while on insulin:

i. Glycosylated hemoglobin level (HbA1C) greater than 7 percent
ii. History of recurring hypoglycemia
iii. Wide fluctuations in blood glucose before mealtime
iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
v. History of severe glycemic excursions; AND

H. The patient has tried and failed an external insulin pump (failure such as: blood glucose control cannot be maintained on an external pump or the member has barriers that cannot allow the use of an external pump) [documentation required]; AND
I. The patient's total daily insulin requirement does not exceed 76 units.

Continuing Insulin Infusion Therapy. Members must meet ALL of the following criteria:

A. The patient is 18 years of age or older; AND
B. The patient requires continuous subcutaneous infusion of either 20 Units, 30 Units, or 40 Units of basal insulin in a 24-hour time period and on-demand dosing of up to 36 Units of bolus insulin in a 24-hour time period; AND
C. The patient is using a rapid-acting insulin product (U-100 only) in the device; AND
D. The patient's total daily insulin requirement does not exceed 76 units; AND
E. The patient is currently on the V-Go device or member has tried and failed an external insulin pump (failure such as: blood glucose control cannot be maintained on an external pump or the member has barriers that cannot allow the use of an external pump) [documentation required].

Initial Approval/ Extended Approval.

A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

V-Go device has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Letter from the FDA to Valeritas regarding status of V-Go device Disposable Insulin Deliver Device. Food and Drug Administration. December 1, 2010. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K100504.pdf
2. Letter from the FDA to Valeritas regarding status of V-Go device Disposable Insulin Deliver Device. Food and Drug Administration. February 23, 2010. Available at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/K103825.pdf
3. Lajara R, Fetchick DA, Morris TL, Nikkel C.Use of V-Go device® Insulin Delivery Device in Patients with Sub-optimally Controlled Diabetes Mellitus: A Retrospective Analysis from a Large Specialized Diabetes System. Diabetes Ther. 2015 Oct 15