Original Effective Date: 08/15/2019
Current Effective Date: 05/31/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C17724-A

Disposable Insulin Delivery Device

PRODUCTS AFFECTED

Omnipod, Omnipod DASH, V-Go 20, V-Go 30, V-Go 40

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Insulin dependent diabetes

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR V-GO DEVICE:
1. Documented diagnosis of Type 2 Diabetes
AND

2. Documentation member will be using either aspart (NovoLog) or lispro (Humalog [U-100]) in the device
   AND
3. Documentation member has been using multiple doses of insulin injections a day (3 injections daily or more)
   AND
4. Prescriber attests member has worked with a provider to adjust dose of insulin for at least 6 months and failed to meet glucose goals
   AND
5. Prescriber attests member does NOT need to make regular adjustments or modifications to their basal rate during a 24-hour period
   AND
6. Prescriber attests member's amount of insulin used at meals does not require adjustments of less than 2-unit increments
   AND
7. Documentation member meets one of the following while on insulin: (i) Glycated 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
8. Documentation member has tried and failed an external insulin pump (failure such as: blood glucose control cannot be maintained on an external pump, or member has barriers or limitations that prohibits the use of an external pump) [DOCUMENTATION REQUIRED]
   AND
9. Documentation member's total daily insulin requirement does not exceed 76 units

B. FOR OMNIPOD/OMNIPOD DASH:
1. Documented diagnosis of Type 1 or 2 Diabetes Mellitus
   AND
2. Prescriber attests that member has completed a diabetes education program within the preceding 24 months
   AND
3. Documentation member has been on a maintenance program for at least SIX months involving at least THREE injections of insulin per day and frequent self-adjustments of insulin dosage
   AND
4. Prescriber attests that member (or someone assisting the individual) is capable of managing the pump and that the desired improvement in metabolic control can be achieved
   AND
5. Documentation member has ANY of the following symptoms or conditions: Glycated hemoglobin level (HbA1c) greater than 7%, A history of recurring hypoglycemia, Wide fluctuations in blood glucose before mealtime, A marked early morning increase in fasting blood sugar (dawn phenomenon- glucose level exceeds 200 mg/dl), or A history of severe glycemic excursions

CONTINUATION OF THERAPY:

A. FOR V-GO DEVICE:
1. Documentation member has been, and will continue to use either aspart (NovoLog) or lispro (Humalog [U-100]) in the device
   AND
2. Documentation member is responding positively to therapy (e.g., lower insulin utilization, decrease in Hgb A1c, increase in compliance, decrease in oral diabetes therapy, decrease in ER visits, etc.)
   AND
3. Prescriber attests member is adherent to provider follow-up visits and training

B. FOR OMNIPOD/OMNIPOD DASH:
1. Documentation member is responding positively to therapy (lower insulin utilization, decrease in Hgb A1c, increase in compliance, decrease in oral diabetes therapy, decrease in ER visits, etc.)
   AND
2. Prescriber attests member is adherent to provider follow-up visits and training
   AND
3. Quantity requested does not exceed 15 per month

DURATION OF APPROVAL:
Initial authorization: 12 months, Continuation of therapy: 12 months

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an endocrinologist or nurse practitioner/physician assistant working with an endocrinologist. Other prescribers, e.g., PCPs, must consult with an endocrinologist or nurse practitioner/physician assistant working with an endocrinologist.

AGE RESTRICTIONS:
None

QUANTITY:
Omnipod: 15/30 days
V-go 20, 30 or 40: Maximum of one strength 30/30 days

PLACE OF ADMINISTRATION:
The recommendation is that disposable devices in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Insulin Administration Supplies

FDA-APPROVED USES:
OMNIPOD: Tubeless, waterproof wearable Pod that provides up to 72 hours of non-stop insulin with an easy-to-use, touchscreen, Bluetooth®-enabled Personal Diabetes Manager (PDM) that looks like a normal smartphone. Intended for the subcutaneous delivery of insulin, at set and variable rates, for the management of diabetes mellitus in persons requiring insulin.

V- GO: Type 2 diabetes with prior multiple daily injections. Indicated for continuous subcutaneous infusion of insulin and on-demand bolus dosing in 2-unit increments in adult patients requiring insulin.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

Nonprogrammable Transdermal Insulin Delivery

Rosenfeld et al. (2012) performed an analysis of glycemic control in twenty-three patients who used the V-Go device. Clinical data was retrospectively collected before V-Go initiation, after 12 weeks of use, at the end of treatment and 12 weeks after discontinuation. Patient perceptions of device use were obtained through telephone surveys. The authors reported that glycemic control improved when patients were switched to the V-Go for insulin delivery and deteriorated when the V-Go was discontinued. No differences in hypoglycemic events were noted. Study limitations include retrospective design, small sample size and short-term follow-up. Further well-designed, prospective studies are needed to establish the safety and efficacy of this device in managing patients with diabetes. Lajara et al. (2016) compared two methods of insulin delivery in patients with uncontrolled type 2 diabetes. Data were obtained using electronic medical records from a large multi-center system. Records were reviewed to identify patients transitioned to the V-Go device or insulin pen when A1c was >7% on basal insulin therapy. One hundred sixteen patients were evaluated (56 V- Go, 60 insulin pen). Both groups experienced significant glycemic improvement from similar mean baselines. Progression to intensified insulin therapy resulted in significant glycemic improvement. Insulin delivery with V-Go was associated with a greater reduction in A1C and required less insulin than patients using an insulin pen. Study limitations include retrospective design and patient-reported outcomes.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Disposable Insulin Delivery Devices are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Omnipod, Omnipod DASH, and Omnipod 5 Insulin Management Systems are not recommended for people who are unable to monitor glucose as recommended by their healthcare provider, are unable to maintain contact with their healthcare provider, and are unable to use the Omnipod system according to instructions. Additionally, for Omnipod 5, it is not recommended for people who are taking hydroxyurea as it could lead to falsely elevated CGM values and result in over-delivery of insulin that can lead to severe hypoglycemia, and for people who do not have adequate hearing and/or vision to allow recognition of all functions of the Omnipod system including alerts, alarms, and reminders.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
A9274*	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories

AVAILABLE DOSAGE FORMS:

Omnipod 5 G6 Intro (Gen 5) KIT
Omnipod 5 G7 Intro (Gen 5) KIT
Omnipod 5 G6 Pods (Gen 5) MISC
Omnipod 5 G7 Pods (Gen 5) MISC
Omnipod Classic PDM (Gen 3) KIT
Omnipod Classic Pods (Gen 3) MISC

Omnipod DASH Intro (Gen 4) KIT
Omnipod DASH PDM (Gen 4) KIT
Omnipod DASH Pods (Gen 4) MISC
Omnipod Go KIT 10UNIT/24HR
Omnipod Go KIT 15UNIT/24HR
Omnipod Go KIT 20UNIT/24HR
Omnipod Go KIT 25UNIT/24HR
Omnipod Go KIT 30UNIT/24HR
Omnipod Go KIT 35UNIT/24HR
Omnipod Go KIT 40UNIT/24HR
V-Go 20 KIT 20UNIT/24HR
V-Go 30 KIT 30UNIT/24HR

V-Go 40 KIT 40UNIT/24HROmnipod Touch Screen Personal Diabetes Manager (PDM) communicates with the Pod and the CONTOUR® NEXT ONE Blood Glucose Meter through Bluetooth® Wireless Technology Omnipod DASH™ System customers will be eligible to receive 1 free PDM every 4 years with the purchase of Pods subject to certain conditions including, but not limited to, verification of insurance. 1-800-591-3455.

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable Revisions: Required Medical Information Continuation of Therapy FDA-Approved Uses Available Dosage Forms References	Q2 2024
REVISION- Notable Revisions: Required Medical Information Continuation of Therapy Prescriber Requirements Contraindications/Exclusions/Discontinuation References	Q2 2023
REVISION- Notable Revisions: References	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file