

External Insulin Infusion Pumps

Override(s)	Approval Duration
Prior Authorization Quantity Limits	1 year

Medications	Quantity Limit
OmniPod Classic	May be subject to quantity limit
OmniPod DASH	
OmniPod 5	
Twist	
OmniPod GO	
V-Go	
CeQur Simplicity	

APPROVAL CRITERIA

Initial requests for external insulin pumps (OmniPod 5, Twist) that WILL be utilized in an automated insulin delivery system (an automated insulin delivery system is comprised of an external insulin pump, continuous glucose monitoring system, and algorithm that automatically adjusts insulin doses based on glucose levels) may be approved when the following criteria are met:

- I. Individual has type 1 diabetes mellitus; **AND**
- II. Individual requires insulin injections multiple times daily or an insulin pump is used for maintenance of blood sugar control; **AND**
- III. Individual or caregiver(s) understand the technology, including use of the device to recognize alerts and alarms; **AND**
- IV. Individual or caregiver(s) demonstrate motivation to use the device correctly and consistently; **AND**
- V. Individual or caregiver(s) will continue participation in a comprehensive diabetes treatment plan; **AND**
- VI. Individual presently has any of the following, despite ongoing management using self-monitoring and insulin administration regimens to optimize care:
 - A. Inadequate glycemic control, demonstrated by HbA1c measurements above target; **OR**
 - B. Persistent fasting hyperglycemia; **OR**

- C. Recurring episodes of hypoglycemia (blood glucose <54 mg/dL); **OR**
- D. Hypoglycemia unawareness that puts the individual or others at risk; **OR**
- E. In children and adolescents with type 1 diabetes who have achieved HbA1c levels below 7.0%, when treatment is intended to maintain target HbA1c levels and limit the risk of hypoglycemia;

AND

- VII. If OmniPod 5, individual is 2 years of age or older; **OR**
- VIII. If Twiist, individual is 6 years of age or older.

Initial requests for external insulin pumps (OmniPod Classic, OmniPod DASH, OmniPod GO, V-Go, or CeQur) that will NOT be used as part of an automated insulin delivery system (an automated insulin delivery system is comprised of an external insulin pump, continuous glucose monitoring system, and algorithm that automatically adjusts insulin doses based on glucose levels) may be approved when the following criteria are met:

- I. Individual has a diagnosis of diabetes mellitus (any type); **AND**
- II. Individual or the individual's caregiver(s) has completed a comprehensive diabetes education program; **AND**
- III. Individual requires insulin injections multiple times daily; **AND**
- IV. Individual requires multiple blood glucose tests/readings daily.

Continued requests for all external insulin pumps for continuous subcutaneous insulin infusion (CSII) may be approved when the following criteria are met:

- I. The device has resulted in clinical benefit (including but not limited to improved or stabilized HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).

Requests for replacement of external insulin pumps (not including disposable external insulin pump parts) may be approved when the following criteria have been met:

- I. The device is out of warranty; **AND**
- II. The device is malfunctioning; **AND**
- III. The device cannot be refurbished.

Requests replacement of an external insulin pump for pediatric individuals (under 18 years of age) who require a larger insulin reservoir will be considered on a case-by-case basis. The following information is required when submitting requests:

- I. Current insulin pump reservoir volume; **AND**
- II. Current insulin needs; **AND**
- III. Current insulin change out frequency required to meet individual needs.

Requests for external insulin pumps for continuous subcutaneous insulin infusion (CSII) may not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons With Diabetes Mellitus. *Endocr Pract*. 2021;27(6):505-537. doi:10.1016/j.eprac.2021.04.008.
5. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes-2024. *Diabetes Care*. 2024;47(Suppl 1):S126-S144. doi:10.2337/dc24-S007.
6. Omnipod Dash User Guide. Available from:..Accessed October 10, 2022.
7. Omnipod 5 User Guide. Available from:..Accessed October 10, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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