

External Insulin Infusion Pumps

Override(s)	Approval Duration
Prior Authorization Quantity Limits	Pump: 1 time Supplies (Pods): 1 year

Medications	Quantity Limit
OmniPod Personal Diabetes Manager (PDM) OmniPod Dash Personal Diabetes Manager (PDM) OmniPod Go V Go CeQur Simplicity OmniPod Pods OmniPod Dash Pods	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for disposable external insulin pumps (with wireless communication capability) and supplies may be approved in any of the following groups (I, II, **or** III) when the following criteria are met:

- I. Individuals with verified diabetes mellitus (any type) meeting *all* the following criteria (A through E):
 - A. Completed a comprehensive diabetes education program within the past 2 years; **AND**
 - B. Follows a program of multiple daily injections of insulin; **AND**
 - C. Has frequent self-adjustments of insulin doses for the past 6 months; **AND**
 - D. Requires multiple blood glucose tests daily or is using a continuous glucose monitor; **AND**
 - E. Has *any* of the following while on a multiple daily injection regimen:
 1. Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent; **OR**
 2. “Brittle” diabetes mellitus with recurrent episodes of diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization; **OR**
 3. History of recurring hypoglycemia or severe glycemc excursions; **OR**
 4. Wide fluctuations in blood glucose before mealtime; **OR**

5. "Dawn phenomenon" with fasting blood sugars frequently exceeding 200 mg/dl; **OR**
 6. Microvascular or macrovascular complications (for example, diabetic retinopathy or cardiovascular disease); **OR**
- II. Individuals has verified diabetes mellitus (any type) and are pre-conception or currently pregnant, to reduce the incidence of fetal mortality or anomaly; **OR**
 - III. Individuals has verified diabetes mellitus (any type) successfully using a continuous insulin infusion pump prior to enrollment and requiring multiple blood glucose tests daily during the month prior to enrollment.

Continued requests for disposable external insulin pumps (with wireless communication capability) may be approved when the following criteria are met:

- I. Individual utilizes the device as intended; **AND**
- II. The device has resulted in desired clinical benefit (including but not limited to improved HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).

Requests for external insulin replacement pumps 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 external insulin replacement pumps 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.

External insulin pumps or supplies (pods) **may not be approved** for any indication other than those listed above.

Use of a disposable external insulin pump with **no** wireless communication capability (for example, OmniPod-Go, V-Go®, CeQur® Simplicity™) **may not be approved** under all circumstances.

Replacement of currently functional and warranted external insulin pumps may not be approved when the replacement of external insulin pumps criteria (I, II, and III) above have not been met.

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. Handelsman Y, Grunberger G, Zimmerman RS, et.al. American Association of Clinical Endocrinologists and American College of Endocrinology – Clinical practice guidelines for developing a diabetes mellitus comprehensive care plan – 2015. *Endocrine Practice*; 21(suppl1); April 2015. Available from: <https://journals.aace.com/doi/pdf/10.4158/EP15672.GLSUPPL>.
5. American Diabetes Association; Professional Practice Committee: *Standards of Medical Care in Diabetes—2022. Diabetes Care* 1 January 2022; 45 (Supplement_1): S3. <https://doi.org/10.2337/dc22-Sppc>.
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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.