Select External Insulin Infusion Pumps (Omnipod® Pods)

Policy # 00834
Original Effective Date: 04/10/2023
Current Effective Date: 04/01/2025

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of select external insulin infusion pumps, including but not limited to Omnipod®‡, Omnipod DASH®‡, Omnipod®‡ 5, and Omnipod GO™‡ to be **eligible for coverage**** for the treatment of patients with a diagnosis of insulin dependent diabetes who meet the following criteria:

Patient Selection Criteria
Coverage eligibility for select external insulin infusion pumps, including but not limited to Omnipod, Omnipod DASH, Omnipod 5, and Omnipod GO will be considered when the following criteria are met:

Note: Insulin pump must be prescribed by an endocrinologist or physician with similar skill and training in the management of external insulin pumps.

- Supporting clinical documentation from either the patient's primary physician or a consulting endocrinologist must be submitted for review when requesting the insulin pump; AND
- The patient/family has completed a comprehensive diabetes education program; AND
- A complete assessment that provides documented evidence of patient/family commitment to self-management of the insulin pump including documentation of very good compliance with the current self-management program; AND
- Patient must be on a program of multiple daily insulin injections (3 or more per day) with frequent self-adjustments of insulin for at least 6 months prior to the initiation of insulin pump therapy; AND
- Patient must have the ability to self-monitor blood glucose levels at least four times/day as documented on a certificate of medical necessity form; AND
- The patient must also meet one or more of the following criteria while on multiple daily insulin injections:
    - Hemoglobin A1c is > 7%; OR
    - History of recurrent hypoglycemia; OR

- Wide fluctuations in blood sugar levels before meals (pre-prandial blood glucose levels frequently exceeding 140 mg/dl); OR
- Presence of Dawn Phenomenon with fasting blood sugar values frequently exceeding 200 mg/dl; OR
- History of severe glycemic excursions (usually associated with brittle diabetes, hypoglycemic unawareness, nocturnal hypoglycemia, extreme insulin sensitivity and/or very low insulin requirements).

Note: Members who have been on insulin pump therapy prior to enrollment with Louisiana Blue must have documentation of glucose self-monitoring at least four times/day during the month prior to enrollment.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of select external insulin infusion pumps, including but not limited to Omnipod, Omnipod DASH, Omnipod 5, and Omnipod GO, when the patient selection criteria are not met to be **investigational.***

Background/Overview

The Omnipod Insulin Management System, Omnipod DASH Insulin Management System, Omnipod 5 Automated Insulin Delivery System, and Omnipod GO are intended for subcutaneous delivery of insulin offering an alternative to traditional insulin pumps and multiple daily injections.

The Omnipod Insulin Management System, also known as Omnipod "Classic" delivers insulin at set and variable rates for the management of diabetes mellitus in persons requiring insulin; it was discontinued on December 31, 2023.

Omnipod DASH Insulin Management System delivers insulin at set and variable rates (basal and bolus) for the management of diabetes mellitus (DM) in persons requiring insulin. Omnipod DASH is indicated for patients with either Type 1 or Type 2 DM and is interoperable with a compatible blood glucose meter to receive and display blood glucose measurements. Omnipod DASH works with a Personal Diabetes Manager (PDM), a handheld device that controls and monitors the Pod's operations using wireless technology. Glucose readings can be logged into the PDM manually or from pairing with its compatible blood glucose meter. Carbohydrate intake can also be entered into the PDM, and the Bolus Calculator can suggest a bolus dose based on glucose readings and carbohydrates.

Omnipod 5 Automated Insulin Delivery System delivers insulin at set and variable rates (basal and bolus) for up to 72 hours (3 days) for the management of DM in persons requiring insulin. It is indicated for patients with Type 1 DM ≥ 2 years of age. Omnipod 5 is able to reliably and securely

communicate with compatible, digitally connected devices, including automated insulin dosing software, to receive, execute, and confirm commands from these devices. Currently, Omnipod 5 is compatible with both the Dexcom®‡ G6 and G7 continuous glucose monitors.

Omnipod GO delivers insulin at a preset basal rate in one 24-hour time period for 3 days (72 hours) in adults with Type 2 DM. Omnipod is a standalone device, available in seven different pre-programmed daily rates, capable of delivering 10 to 40 units per day continuously at its prefixed rate. Omnipod GO is compatible with U-100 rapid acting insulin.

For Omnipod, Omnipod DASH, and Omnipod 5, the pods should be replaced at least once every 72 hours or after delivering 200 units of U-100 insulin, whichever comes first. The type of insulin used in the pod may also determine how frequently the pod needs to be changed. Pods are not interchangeable between the different Omnipod systems. For example, Omnipod Pods will not be compatible with an Omnipod DASH system.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

References

1. Diabetes- Omnipod Pods Drug Quantity Management Policy-Per Days. Express Scripts. September 2022.
2. Omnipod Insulin Management System [user guide]. Acton, MA: Insulet; May 2021. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-System_User-Guide_English.pdf
3. Omnipod DASH Insulin Management System [user guide]. Acton, MA: Insulet; October 2023. Available at: https://www.omnipod.com/sites/default/files/2021-04/Omnipod-DASH_User-Guide_English.pdf
4. Omnipod 5 Automated Insulin Delivery System [user guide]. Acton, MA: Insulet; October 2023. Available at: https://www.omnipod.com/sites/default/files/Omnipod-5_User-guide.pdf
5. Omnipod GO Insulin Delivery Device [Quick Start Guide]. Acton, MA: Insulet; October 2023 Available at https://www.omnipod.com/sites/default/files/GOQuickStartGuideUSEnglish.pdf.

Policy History

Original Effective Date: 04/10/2023
Current Effective Date: 04/01/2025
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. New policy.

Policy # 00834
Original Effective Date: 04/10/2023
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03/07/2024	Medical Policy Committee review
03/13/2024	Medical Policy Implementation Committee approval. Added a new product, Omnipod GO, to the policy.
03/06/2025	Medical Policy Committee review
03/12/2025	Medical Policy Implementation Committee approval. Updated background information regarding current product information for all Omnipod systems.

Next Scheduled Review Date: 03/2026

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.