

Diabetic Equipment, Supplies, and Accessories

LOB(s): ⊠ Commercial	State(s):	Montana	☐ Other:
⊠ Medicaid	⊠ Oregon	☐ Washington	

Enterprise Policy

PacificSource is committed to assessing and applying current regulatory standards, widely-used treatment guidelines, and evidenced-based clinical literature when developing clinical criteria for coverage determination. Each policy contains a list of sources (references) that serves as the summary of evidence used in the development and adoption of the criteria. The evidence was considered to ensure the criteria provide clinical benefits that promote patient safety and/or access to appropriate care. Each clinical policy is reviewed, updated as needed, and readopted, at least annually, to reflect changes in regulation, new evidence, and advancements in healthcare.

Clinical Guidelines are written when necessary to provide guidance to providers and members in order to outline and clarify coverage criteria in accordance with the terms of the Member's policy. This Clinical Guideline only applies to PacificSource Health Plans, PacificSource Community Health Plans, and PacificSource Community Solutions in Idaho, Montana, Oregon, and Washington. Because of the changing nature of medicine, this list is subject to revision and update without notice. This document is designed for informational purposes only and is not an authorization or contract. Coverage determinations are made on a case-by-case basis and subject to the terms, conditions, limitations, and exclusions of the Member's policy. Member policies differ in benefits and to the extent a conflict exists between the Clinical Guideline and the Member's policy, the Member's policy language shall control. Clinical Guidelines do not constitute medical advice nor guarantee coverage.

Background

PacificSource Health Plans supports members in screening and appropriate treatment for the diagnosis of diabetes. This includes coverage of appropriate durable medical equipment supplies, and accessories for monitoring and maintaining healthy blood glucose levels.

Glucose monitors, supplies, and accessories are covered when medical necessity criteria are met. In addition, PacificSource utilizes Center for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) to determine maximum quantities and frequencies for diabetic supply purchases.

Criteria

Commercial

I. Blood Glucose Monitors (BGM) (hand-held or stand-alone device)

PacificSource considers the coverage of a blood glucose monitors, supplies, and accessories medically necessary when **ALL** the following conditions are met:

- A. The member has a diagnosis of Diabetes Mellitus
- B. Member or responsible individual/caregiver is capable of using the device as prescribed
- **C.** The device is designed for personal use

II. Specialty Blood Glucose Monitors

- **A.** BGM with special features (HCPC codes E2100 and E2101) are covered when the criteria for Blood Glucose Monitors are met **AND** the prescriber certifies the member or caregiver has **ONE** of the following:
 - A severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) requiring the use of a special monitoring system (E2100)
 - An impairment of manual dexterity severe enough to require the use of a special monitoring system (E2101)

III. Continuous Glucose Monitors (CGM)

Prior authorization is required for CGM monitors, transmitters, and sensors (codes E2102, E2103, A4238, A4239, A9276, A9277, and A2978).

A. Non-Adjunctive (Therapeutic) Devices (preferred devices Freestyle Libre & Dexcom) will be processed under the Pharmacy benefit with the exception of 1) Billings Clinic, 2) City of Eugene, 3) Deschutes County for which the following criteria will be used.

PacificSource considers the coverage of therapeutic Continuous Glucose Monitors, supplies, and accessories medically necessary when **ALL** the following criteria are met:

- 1. The member has diagnosis of Diabetes Mellitus
- 2. The member is currently on insulin treatment of at least three (3) subcutaneous (SubQ) injections daily or uses an insulin pump
- **3.** The member performs at least four (4) blood glucose tests per day with a blood glucose monitoring device (prior to CGM)
- 4. The member requires frequent insulin adjustments based on blood glucose readings
- **5. Excludes CGM for Temporary use** (e.g., during dialysis treatments or for nutritional / blood sugar information)

B. Adjunctive (Non-Therapeutic) Devices

PacificSource <u>DOES NOT</u> consider Non-Therapeutic continuous glucose monitors and supplies to be medically necessary. These devices are <u>not covered under medical benefits</u>, as they do not replace the standard process of blood glucose monitoring.

IV. Implantable Continuous Glucose Monitors (I-CGM)

Prior authorization is required (0446T, 0447T, 0448T).

- **A.** PacificSource considers the coverage of Implantable Continuous Glucose Monitors (I-CGM), implantation, to be medically necessary when **ALL** of the following criteria is met:
 - 1. Member is 18 years of age and older
 - 2. Diagnosis of Diabetes Mellitus
 - 3. The member is currently on insulin treatment of at least three (3) subcutaneous (SubQ) injections daily or uses an insulin pump
 - **4.** The member performs at least four (4) blood glucose tests per day with a blood glucose monitoring device

- 5. The member requires frequent insulin adjustments based on blood glucose readings
- **6.** <u>Excludes I-CGM for Temporary use</u> (e.g., during dialysis treatments or for nutritional / blood sugar information)
- **B.** PacificSource considers the removal or replacement of an implantable continuous glucose monitor to be medically necessary when **ONE** of the following are met:
 - 1. The member's device is no longer needed
 - 2. Member's sensor fails or device lifespan has expired

V. Insulin and Syringes

Diabetic insulin and syringes are covered expenses under the prescription drug benefit only. Any receipts submitted for reimbursement will process under the pharmacy benefit. If the member does not have a prescription drug benefits insulin and syringes are not coverable.

VI. Other Supplies

Supplies such as lancets, test strips, glucostix, and needle free injection devices can be covered under the medical plan's durable medical equipment (DME) benefit or the prescription drug benefit.

VII. Benefit Coverage

PacificSource members may choose to purchase their diabetic supplies utilizing their pharmacy or DME benefit.

A. Pharmacy Coverage

Members who choose to purchase monitors, supplies, and/or accessories from the pharmacy utilize their prescription benefit. Please see the PacificSource Diabetic Supply formulary online for pharmacy benefit coverage and limitations.

B. DME Coverage

If the member chooses to purchase diabetic supplies (e.g., lancets and test strips) from a DME provider, these supplies will be reimbursed using the members DME benefit. Reimbursement is based upon the providers participating or non-participating status, as well as the contracted or allowed amount.

- 1. Members may purchase test strips or lancets with a maximum of 300 count for a 30-day supply or 900 count for a 90-day. Refills may be filled within 10 days of supply exhaustion. Requests for coverage of orders exceeding the supply limit require prior authorization approval.
- **2.** Insulin infusion pumps **do not** require prior authorization. However, the insulin cartridge **does** require prior authorization through the Pharmacy benefit.

Medicaid

PacificSource Community Solutions (PCS) follows Oregon Administrative Rules (OARs) 410-141-3820 through 3830, 410-151-0000 through 0003, 410-122-0730, and Guideline Note 108 of the OHP Prioritized List of Health Services for the coverage of continuous blood glucose monitors.

PacificSource Community Solutions (PCS) follows Oregon Administrative Rules (OARs) 410-141-3820 through 3830, 410-151-0000 through 0003, and 410-122-0520 for glucose monitors and supplies and

Ancillary Guideline A2 of the OHP Prioritized List of Health Services for self-monitoring of blood glucose in diabetes.

Medicare

PacificSource Medicare follows CMS National Coverage Determinations and Local Coverage Determination for home blood glucose monitors, continuous blood glucose monitors, I-CGM, supplies and accessories:

- National Coverage Determinations (NCD) 40.2 for Home Blood Glucose Monitors
- Local Coverage Determination (LCD) Glucose Monitors L33822
- Local Coverage Determination (LCD) Implantable Continuous Glucose Monitors (I-CGM) L38659
- Local Coverage Determination (LCD) External Infusion Pumps L33794

Coding Information

The following list of codes are for informational purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Equipment

HCPC Code	Description	Maximum Units	Frequency
E0607	Home blood glucose Monitor	1 unit (each)	3 years/1095 days
E1399	DME, miscellaneous		
E2100	Blood glucose monitor w/integrated voice synthesizer	1 unit (each)	3 years/1095 days
E2101	Blood glucose monitor with integrated lancing/blood sample	1 unit (each)	3 years/1095 days
E2102	Adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver	NA	NA
E2103	Non-adjunctive, nonimplanted continuous glucose monitor (CGM) or receiver	1 unit (each)	5 years/1825 days

Supplies and Accessories (not all inclusive)

HCPC Code	Description	Maximum Units	Frequency
A4238	Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories	3 (1unit = 1 month supply)	3 months / 90 days

A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories	3 (1unit = 1 month supply)	3 months / 90 days
A4253	Blood glucose test or reagent strips for home blood glucose monitor	18 units (1 unit = 50 test strips)	3 months / 90 days
A4258	Spring-powered device for lancet	2 unit (each)	1 year / 365 days
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)	90 (1unit = 1 day supply)	3 months / 90 days
A9277	Transmitter; external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)	5 unit (each)	5 years / 1825 days
A2978	Receiver (monitor); external, for use with nondurable medical equipment interstitial continuous glucose monitoring system (CGM)	1 unit (each)	5 years / 1825 days

Professional Fees

CPT, HCPC, Modifier	Description
95249	Professional fee for patient-supplied equipment
95250	Professional fee for provider- supplied equipment
95251	Professional fee for device interrogation/interpretation
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T	Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision

0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor
Modifier 25	For two of the above codes (95249, 95250, 95251) on the same date of service

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Definitions

- **Blood Glucose Monitor (BGM)** a stand-alone device where the member uses a lancet to obtain a blood sample and place the sample on a test strip that is inserted to the hand-held device.
- **Insulin Pump (external)** a system of administration of continuous subcutaneous insulin through a subcutaneous needle or catheter, battery-operated, and usually worn about the waist.
- **Implantable Continuous Glucose Monitor** includes a fluorescence-based sensor (subcutaneously implanted), smart transmitter, and a mobile application for displaying glucose values, trends, and alerts on the member's compatible mobile device. The life span of the implanted sensor is usually between 90- 180 days).
- Non-Therapeutic(adjunctive) Continuous Glucose Monitor A sensor just under the skin that measures the member's glucose level 24-hours a day. Non-therapeutic devices require the member verify their glucose levels with a stand-alone home blood glucose monitor (BGM) to confirm testing results prior to making treatment decisions.
- **Therapeutic (non-adjunctive) Continuous Glucose Monitor** A sensor just under the skin that measures the member's glucose level 24-hours a day. Therapeutic devices are used to make treatment decisions without the need for a stand-alone home blood glucose monitor (BGM) to confirm testing results

Related Policies

Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DME POS)

References

Centers for Medicare & Medicaid Services (CMS). (April 16, 2023). Glucose Monitor - Policy Article, A5264. https://www.cms.gov/medicare-coverage-database/view/article.aspx?

Centers for Medicare & Medicaid Services (CMS). (April 16, 2023). Local Coverage Determination (LCD) for Glucose Monitors (L33822) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822

Centers for Medicare & Medicaid Services (CMS). (June 19, 2006). National Coverage Determination (NCD) for Home Blood Glucose Monitors (40.2). https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?

Grunberger, G., Sherr, J., Allende, M., Blevins, T., Bode, B., Handelsman, Y., et al. (2021). American Association of Clinical Endocrinology Clinical Practice Guideline: The Use of Advanced Technology in the Management of Persons with Diabetes Mellitus. Endocrine Practice, 27(6), 505–537. https://doi.org/10.1016/j.eprac.2021.04.008

Social Security Act 1861(s)(6) https://www.ssa.gov/OP Home/ssact/title18/1861.htm

U.S. Department of Health & Human Services. (2019). Medicare Fee-for-Service Supplemental Improper Payment Data. https://www.cms.gov/files/document/2019-medicare-fee-service-supplemental-improper-payment-data.pdf

Appendix

Policy Number:

Effective: 4/29/2012 **Next review:** 6/1/2025

Policy type: Commercial

Author(s):

Depts.: Health Services, Customer Service, Claims; Pharmacy

Applicable regulation(s): Social Security Act 1861(s)(6), NCD 40.2, LCD L33822, LCD L38659, LCD L33794, OARs 410-141-3820 through 3830, 410-151-0000 through 0003, 410-122-0520, 410-122-0730, Ancillary Guideline A2, Guideline Note

108 of the OHP Prioritized List

Commercial Ops: 10/2024

Government Ops: 11/2024