

# Medicare Medical Policy

## Implantable and Non-Covered Diabetes Management Technology

MEDICARE MEDICAL POLICY NUMBER: 25

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**INSTRUCTIONS FOR USE:** Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

**SCOPE:** Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

## PRODUCT AND BENEFIT APPLICATION

Medicare Only

### MEDICARE COVERAGE CRITERIA

**IMPORTANT NOTE:** More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

**Notes:** This policy does not address all advanced diabetes management technologies. It is limited to the items and services listed in the “Criteria” table. Items and services not addressed in this medical policy may be considered medically necessary, unless addressed in a separate Medicare medical policy (see Policy Cross References). In addition, external and disposable continuous glucose monitors (CGMs) are **not** addressed by this medical policy, but are addressed by Pharmacy policy.

Service	Medicare Guidelines
<i>Implantable Insulin Infusion Pumps (HCPCS E0782, E0783, E0786)</i>	National Coverage Determination (NCD) for Infusion Pumps ( <a href="#">280.14</a> ) (See Criterion C.2.)
<i>Implantable Continuous Glucose Monitors (e.g., Eversense CGM System) (I-CGM; CPT codes 0446T, 0447T, or 0448T)</i>	Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) ( <a href="#">L38657</a> )
According to the <a href="#">Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule</a> , coverage and payment of any service, device, or equipment requires that service, device or equipment <b>fall under a Medicare-covered benefit category</b> .	
<i>Mobile Apps (e.g., t: connect®, Glooko, Dexcom Share2 App, Dexcom Follow, Dexcom CLARITY® Reports App, MiniMed Connect)</i>	According to the <a href="#">Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.8 – DMEPOS Benefit Category Determinations</a> , “[s]oftware applications (apps) are not devices, equipment, or supplies and do not fall under a DMEPOS benefit category” and “[d]igital therapies or computer software are housed on non-medical devices like smartphones or computers and the equipment and software as a whole are not DME.” Therefore, these health technologies are <b>not a covered benefit</b> for Medicare Plan members.
<i>Remote glucose monitoring devices (e.g., mySentry)</i>	According to the Medicare Pricing, Data Analysis and Coding (PDAC) contractor, the mySentry™ device is to be reported with

	HCPCS code A9279 ( <i>Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified</i> ), and as such, is <b>not a covered benefit</b> for Medicare Plan members. This device, and others like it, will be considered not covered if reported with any other HCPCS code as well.
<i>Hypoglycemic wristband alarm (e.g., Diabetes Sentry™)</i>	According to the Medicare Pricing, Data Analysis and Coding (PDAC) contractor, the Diabetes Sentry™ device is to be reported with HCPCS code A9280 ( <i>Alert or alarm device, not otherwise classified</i> ), and as such, is <b>not a covered benefit</b> for Medicare Plan members. This device, and others like it, will be considered not covered if reported with any other HCPCS code as well.

**Medicare Coverage Criteria:** “MA organizations may create publicly accessible internal coverage criteria... when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs.” (§ 422.101(b)(6) – see [Policy Guidelines](#) below)

- **Medicare Coverage Manuals:** Medicare does not have criteria for diabetes management software in a coverage manual.
- **National Coverage Determination (NCD):** Medicare does not have an NCD for diabetes management software
- **Noridian J-D DMEPOS Local Coverage Determination (LCD)/Local Coverage Article (LCA):** As of the most recent policy review, neither DME Medicare Administrative Contractor (MAC) has an LCD or LCA for diabetes management software, and no Part B MAC maintains an LCD or LCA for this health care technology either.
- Therefore, in the absence of established Medicare coverage criteria in a manual, NCD, LCD, or other regulatory guidance for the health plan’s service area, Company criteria below are applied for medical necessity decision-making. In this case, Medicare coverage criteria are considered “not fully established” as defined under CFR § 422.101(6)(i)(C) as there is no Medicare coverage criteria available.
- **NOTE:** *The summary of evidence, as well as the list of citations/references used in the development of the Company’s internal coverage criteria, are publicly available and can be found using the Company medical policy link below [CFR § 422.101(6)(ii)(A) and (B)].*

<i>Diabetes management software (e.g., Dexcom CLARITY®, FreeStyle CoPilot Health Management System, Medtronic CareLink® system, d-NAV® System) (CPTs 0740T, 0741T)</i>	Company medical policy for <a href="#">Advanced Diabetes Management Technology</a> I. This technology is considered <b>not medically necessary</b> for Medicare based on the Company medical policy. <i>See Policy Guidelines below.</i>
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**IMPORTANT NOTICE:** While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member’s benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization

determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. (*Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021*)

## POLICY CROSS REFERENCES

### MEDICAL

- [Blood Glucose Monitor and Supplies](#), MP276

### PHARMACY

- Medicare Pharmacy Policy: Continuous Glucose Monitors for Personal Use

The full Company portfolio of Medicare Medical Policies is available online and can be [accessed here](#).

## POLICY GUIDELINES

### MEDICARE AND MEDICAL NECESSITY

Only medically reasonable and necessary services or items which treat illness or injury are eligible for Medicare coverage, as outlined in *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. MA organizations (MAOs) make medical necessity determinations based on coverage and benefit criteria, current standards of care, the member's unique personal medical history (e.g., diagnoses, conditions, functional status, co-morbidities, etc.), physician recommendations, and clinical notes, as well as involvement of a plan medical director, where appropriate. (*§ 422.101(c)(1)*)

In addition:

“MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely-used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.” (*§ 422.101(b)(6) and Medicare Managed Care Manual, Ch. 4, §90.5*)

The Plan Medicare medical policy for *PHA Medicare Medical Policy Development and Application* ([MP50](#)) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare

references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development.

While Medicare has coverage criteria for CGMs, there are not fully established Medicare coverage criteria for diabetes software systems (e.g., Dexcom CLARITY®, FreeStyle CoPilot Health Management System, Medtronic CareLink® system, d-NAV® System) (CPTs 0740T, 0741T) available in applicable Medicare statutes, regulations, NCDs or LCDs, then Company medical policy criteria will be applied. The Company medical policy non-coverage position is consistent with the above noted Medicare references.

## **REGULATORY STATUS**

### **U.S. FOOD & DRUG ADMINISTRATION (FDA)**

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

## **BILLING GUIDELINES AND CODING**

### **GENERAL**

See associated local coverage articles (LCAs) for related billing and coding guidance, as well as additional coverage and non-coverage scenarios and frequency utilization allowances and limitations:

- LCA: Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) ([A58133](#))

### **Implantable Continuous Glucose Monitors (I-CGMs)**

Implantation and removal with or without replacement of an implantable continuous glucose monitor (I-CGM) which meets the appropriate criteria found in LCD L38659 (as of 10/23/2025, LCD L38657) are reported with the following codes:

- 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, including system activation

### **Implantable Interstitial Glucose Sensor**

According to Federal Register, 0446T and 0448T describe "services related to insertion, and removal and insertion of an implantable 180-day interstitial glucose sensor."

HCPCS codes G0564 and G0565 were for a 365 day system "related to a newly FDA approved implantable 365-day continuous glucose monitoring system." However, these codes were deleted effective April 1, 2025.

CODES*		
CPT	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, including system activation
	0740T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial set-up and patient education
	0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days
HCPCS	A9270	Non-covered item or service
	A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
	A9280	Alert or alarm device, not otherwise classified
	A9999	Miscellaneous DME supply or accessory, not otherwise specified
	E0782	Infusion pump, implantable, non-programmable (includes all components, e.g., pump, catheter, connectors, etc.)
	E0783	Infusion pump system, implantable, programmable (includes all components, e.g., pump, catheter, connectors, etc.)
	E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)
	E1399	Durable medical equipment, miscellaneous

**\*Coding Notes:**

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. (*Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services*)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- See the non-covered and prior authorization lists on the Company [Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website](#) for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and

Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

## REFERENCES

1. Centers for Medicare and Medicaid Services (CMS). Medicare Physician Fee Schedule (PFS) Relative Value Files. Updated 11/25/2024. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files>. Accessed 3/3/2026.

## POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)
6/2023	Annual review; Added replacement criteria, history of Medicare CGM coverage/coding, and codes A9279, E0782, E0783, E0786, S1030, S1031 to policy
7/2023	Interim update; no change to criteria
5/2024	Annual review; no change to criteria
8/2024	Interim update; update to configuration of A4224
1/2025	Q1 2025 code updates
4/2025	Q2 2025 code updates
6/2025	Annual review; add mobile apps, remote monitoring devices, wristband alarms, & Diabetes management software; use Company criteria when no Medicare policy exists; clarified expected utilization frequency for supplies. (10/24/2025: Replaced L38659 with L38657 and updated companion LCA due to Noridian JF consolidation with JE LCD policies)
4/2026	Annual review; no change to criteria
6/2026	Interim update; Title update. Remove CGMs (transferred to Pharmacy) and external insulin infusion pumps from scope of policy