Medicare Medical Policy

Advanced Diabetes Management Technology

MEDICARE MEDICAL POLICY NUMBER: 25

Effective Date: 6/1/2025

Last Review Date: 3/2025

Next Annual Review: 3/2026

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:

- The following advanced diabetes management technologies are **not addressed by this medical policy**, but are **reviewed by Providence Health Plan's Pharmacy Department**. If approved, these devices will be made available at the member's pharmacy at applicable durable medical equipment cost-share.

• **Insulin Pump**	• **Continuous Glucose Monitors**
• Omnipod • V-Go	• Freestyle Libre • Dexcom

Service	Medicare Guidelines
Continuous Glucose Monitors (CGMs) and related supplies	Local Coverage Determination (LCD): Glucose Monitors Devices (L33822) • ***Therapeutic (non-adjunctive) CGM systems*** *(HCPCS codes E2103 and A4239)* • ***Non-Therapeutic (adjunctive) CGM systems*** *(HCPCS codes E2102 and A4238)* • ***Non-covered CGM systems*** *(HCPCS code A9279)* **NOTES** • **Follow-up Visits:** The LCD requires a follow-up visit every 6 months with the treating practitioner, via either an in-person visit or a Medicare-approved telehealth visit. For Medicare coverage purposes, a pharmacist is not considered a treating practitioner, and therefore, a pharmacist entry in the record does **not** meet this requirement. (Noridian)

	• **History of CGM coverage:** See below for information regarding the history and evolution of CGM coverage under Medicare, including 2023 coverage expansions and exclusions.
HCPCS Codes A9276-A9278	These codes do not represent Medicare-eligible CGM systems. See the Noridian web page for Noncovered Items and see "Billing Guidelines" below for more information about these codes.
External Insulin Infusion Pump (HCPCS codes E0784)	LCD: External Infusion Pumps (L33794) (*Note: see criterion IV.*)
Integrated Insulin Infusion Pumps with CGM Sensing Capabilities	• LCD: External Infusion Pumps (L33794) • LCD: Glucose Monitors Devices (L33822) Notes: • According to LCD L33794, both HCPCS code combinations of K0554/E0784 and E2102/E0784 require the patient to meet **both** insulin pump **and** CGM coverage criteria. • See "Policy Guidelines" below for more information regarding the Guardian™ Connect System. This system may be covered or non-covered, depending on how used. *See "Billing Guidelines" below for more information on these integrated devices and how to code them for claim submission.*
CGM devices without a standalone receiver	LCA: Glucose Monitor - Policy Article (A52464) **NOTE:** Medicare coverage may be available for a CGM system supply allowance if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used **in conjunction with** the durable CGM receiver (code E2102 or E2103); however, CGM devices that **rely solely** on a smart device (e.g., smartphone, tablet, etc.) to display results and do **not** have a stand-alone receiver or integration into an insulin infusion pump do not meet the definition of DME and will be denied as non-covered (no benefit).
Implantable Insulin Infusion Pumps (HCPCS E0782, E0783, E0786)	National Coverage Determination (NCD) for Infusion Pumps (280.14) *(See Criterion C.2.)*
Implantable Continuous Glucose Monitors (I-CGM; CPT codes 0446T, 0447T, or 0448T)	Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (L38659)
Replacement of CGMs or insulin pumps	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.2.C. – Replacement

	Standard Medicare DME replacement rules apply. Primary factors considered will include, but may not be limited to, **all** of the following: • Whether the item is being rented or is member owned; • Reason for replacement (e.g., change in medical condition, lost, stolen, worn out, damaged, etc.); • Whether or not the 5-year reasonable useful lifetime (RUL) for the device has been reached; **and** • Whether or not the item is still under manufacturer warranty. See Policy Guidelines below for specific information regarding replacement requests.
According to the Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.2 – Basic Rule, coverage and payment of any service, device, or equipment requires that service, device or equipment **fall under a Medicare-covered benefit category**.	
Mobile Apps (e.g., t: connect®, Glooko, Dexcom Share2 App, Dexcom Follow, Dexcom CLARITY® Reports App, MiniMed Connect)	According to the Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.8 – DMEPOS Benefit Category Determinations, "[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 **not a covered benefit** for Medicare Plan members.
Remote glucose monitoring devices (e.g., mySentry)	According to the Medicare Pricing, Data Analysis and Coding (PDAC) contractor, the mySentry™ device is to be reported with HCPCS code A9279 *(Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified)*, and as such, is **not a covered benefit** for Medicare Plan members. This device, and others like it, will be considered not covered if reported with any other HCPCS code as well.
Hypoglycemic wristband alarm (e.g., Diabetes Sentry™)	According to the Medicare Pricing, Data Analysis and Coding (PDAC) contractor, the Diabetes Sentry™ device is to be reported with HCPCS code A9280 *(Alert or alarm device, not otherwise classified)*, and as such, is **not a covered benefit** 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)].*

Diabetes management software (e.g., Dexcom CLARITY®, FreeStyle CoPilot Health Management System, Medtronic CareLink® system, d-NAV® System) (CPTs 0740T, 0741T)	Company medical policy for Advanced Diabetes Management Technology I. This technology is considered **not medically necessary** for Medicare based on the Company medical policy. *See Policy Guidelines below.*

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

- Pharmacy Policy: Continuous Glucose Monitors for Personal Use (Non-professional): FreeStyle Libre

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

BACKGROUND

Under Medicare, continuous glucose monitors (CGMs) include both therapeutic (non-adjunctive) and non-therapeutic (adjunctive CGMs). Medicare defines these different systems as follows:

> "A therapeutic or non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. A non-therapeutic or adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions." *(LCD L33822)*

Guardian Connect

Some products may be covered ***or*** non-covered, based on how they are used for an individual member. The Guardian™ Connect System includes disposable glucose sensors and transmitters which work in conjunction with a smart device and software app ***OR*** with certain MiniMed insulin infusion pumps. This system does not have a dedicated durable receiver to meet the Medicare definition of DME.[1] If used **without** integration with an insulin pump (using only a smart phone or other device), the Guardian Connect System would **not** meet the Medicare definition of DME. However, if used with a medically necessary insulin pump, when the medical necessity criteria for CGMs are met, this CGM system may be considered medically necessary.

In addition to CGMs, other diabetes management systems are also available.

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 Company 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.

Since there are not fully established Medicare coverage criteria for diabetes software system 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.

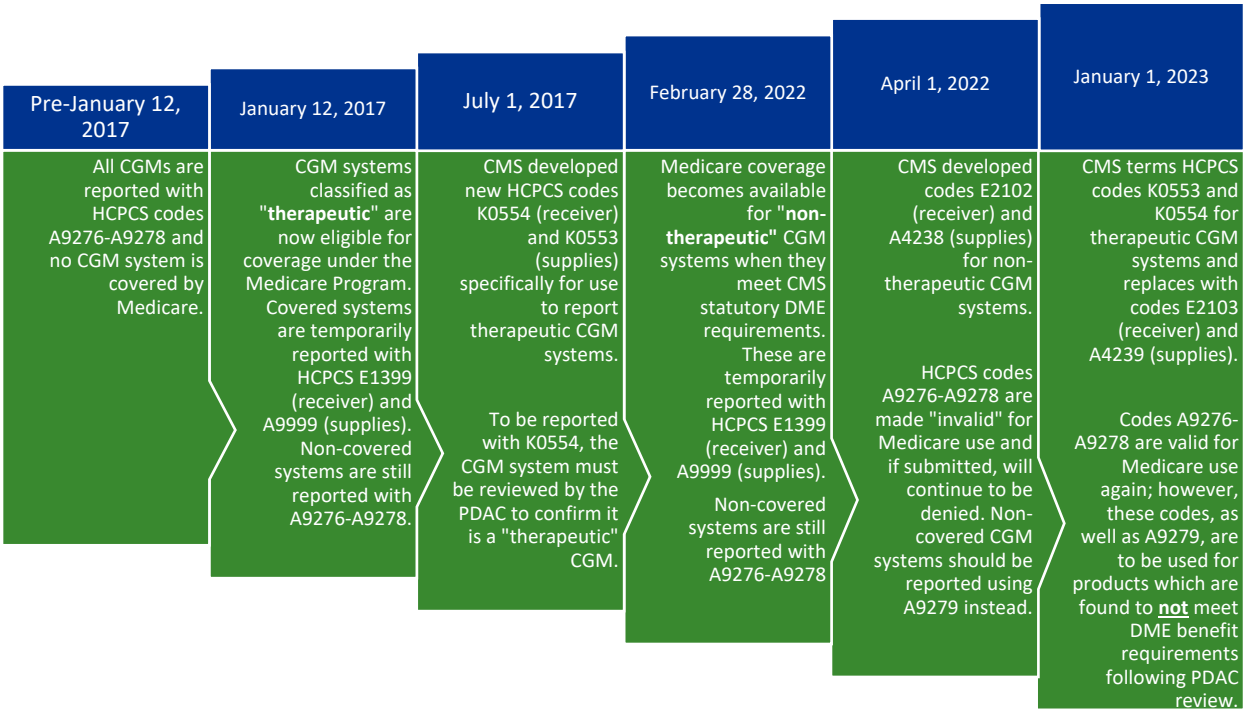
REGULATORY STATUS

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

HISTORY OF MEDICARE CGM COVERAGE AND ASSOCIATED CODING



Prior to January 2017, no CGM system was covered by the Medicare Program. All CGM systems at that time required their readings be confirmed and verified by fingerstick testing using a home blood glucose test system before making diabetes treatment decisions (e.g., change in diet or insulin dosage). That means the CGM itself was not what was 'treating or diagnosing' any condition, it was simply an added step in the blood testing process. Therefore, they were not considered DME, as they did not a serve medically reasonable or necessary purpose to treat or diagnosis an illness or condition.[1]

In December 2016, the first "therapeutic" CGM was approved by the FDA. These therapeutic CGMs did not require a finger stick to confirm and verify their readings, meaning adjustments to insulin could be made using the CGM alone. This meant therapeutic CGMs could now meet Medicare's medical necessity criteria for coverage, while non-therapeutic models continued to be ineligible.[1]

Over the years since 2016, Medicare's coverage of CGMs has evolved, including the coverage of individuals who are not insulin-treated, but who have a history of hypoglycemic events. In April of 2023, Medicare expanded coverage of CGMs to individuals who are **not** insulin treated, updating the LCD with the following evidence summary:

> *"The requirement for frequent adjustment of the beneficiary's insulin treatment regimen on the basis of BGM or CGM testing results has been removed. The requirement for a visit with the treating practitioner every six months to assess adherence has been retained and language clarified to specifically address the long-standing policy which allows for the use of Medicare - approved telehealth visits. Additionally, elimination of the intensive insulin management requirement and the inclusion of telehealth options may also promote health equity for vulnerable rural and non-Asian ethnic minorities, as well as Medicare beneficiaries in areas with*

healthcare-professional shortages. CGM coverage has not been extended to patients solely on the basis on having stage 3-5 chronic kidney disease, gestational diabetes mellitus, bariatric surgery, or pancreatectomy who do not otherwise meet the outlined coverage criteria. Additional coverage criteria have been added to ensure the CGM is being used in accordance with FDA indications and the beneficiary has received proper training in the use of the device…" (4/2023 Version of LCD L33822)

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: Glucose Monitor – Policy Article (A52464)
    - This LCA includes medically necessary ICD-10 codes, which are based on the above evidence summary.
- LCA: Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) (A58138)
- LCA: External Infusion Pumps (A52507)

Important Note: Even though some non-therapeutic (adjunctive) CGMs may now be eligible for coverage under Medicare, not all CGM systems meet Medicare's DME requirements. All CGMs billed to Medicare using HCPCS code E2102 must be reviewed for correct coding by the Medicare Pricing, Data Analysis and Coding (PDAC) contractor and be listed on the PDAC Product Classification List (PCL). If a CGM system is billed using HCPCS code E2102, but the CGM system is not on the PCL for this HCPCS code, then the claim may be denied for incorrect coding. **Proper HCPCS coding is critical for appropriate claim adjudication, benefit application, and member cost sharing.**

Table 3: PDAC Assigned Coding

Note: This information was accurate at the time of the most recent policy review, but is subject to be changed by the PDAC Contractor at any time. The PDAC PCL list should be checked to verify product categorization and code assignment. In addition, inclusion on this list does not guarantee the device is addressed by this policy. Some devices may be subject to Pharmacy benefits instead.

Product/Device Name	Manufacturer	HCPCS Code(s)
Therapeutic CGM Systems		
Dexcom G5 Mobile Continuous Glucose Monitoring (CGM) System	DexCom	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies) **7/1/2017-12/31/2022:** K0554 (Receiver) and K0553 (Supplies)
Dexcom G6 Mobile Continuous Glucose Monitoring (CGM) System	DexCom	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies) **1/1/2020-12/31/2022:** K0554 (Receiver) and K0553 (Supplies)
Freestyle Libre Flash Glucose Monitoring System	Abbott Diabetes Care Inc.	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies)

		12/27/2017-12/31/2022: K0554 (Receiver) and K0553 (Supplies)
Freestyle Libre 2 Flash Glucose Monitoring System	Abbott Diabetes Care Inc.	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies) **8/5/2020-12/31/2022:** K0554 (Receiver) and K0553 (Supplies)
Freestyle Libre 3 CGM System	Abbott Diabetes Care Inc.	**PDAC approved on 6/15/2023:** E2103
G5 Mobile CGM Touchscreen Receiver	DexCom	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies) **1/2/2018-12/31/2022:** K0554 (Receiver) and K0553 (Supplies)
G6 Mobile CGM Touchscreen Receiver	DexCom	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies) **6/22/2018-12/31/2022:** K0554 (Receiver) and K0553 (Supplies)
T:Slim X2 Insulin Pump Interoperable with Basal-IQ Technology	Tandem Diabetics Care	**1/1/2023:** E0784 ***OR*** E0784 + E2103 **1/1/2020-12/31/2022:** E0784 ***OR*** E0784 + K0554
T:Slim X2 Insulin Pump Interoperable with Control-IQ Technology	Tandem Diabetics Care	**1/1/2023:** E0784 ***OR*** E0784 + E2103 **1/1/2020-12/31/2022:** E0784 ***OR*** E0784 + K0554
iLet Insulin Pump System	Beta Bionics	**PDAC approved on 9/19/2023:** E0784 ***OR*** E0784 + E2103
Non-Therapeutic CGM Systems		
Minimed 630G System with Guardian Sensor 3 or Enlite Sensor	Medtronic Diabetes	**7/1/2022:** E0784 + E2102 ***OR*** E0784 + E2102 + E0607 *(Prior to 7/1/2022, reported only with E0784)*
Minimed 670G System with Guardian Sensor 3	Medtronic Diabetes	**7/1/2022:** E0784 + E2102 ***OR*** E0784 + E2102 + E0607 *(Prior to 7/1/2022, reported only with E0784)*
Minimed 770g System with Guardian Sensor 3	Medtronic Diabetes	Effective 7/1/2022: E0784 + E2102 ***OR*** E0784 + E2102 + E0607 *(Prior to 7/1/2022, reported only with E0784)*

Minimed 780g System with Guardian Sensor 3 or 4	Medtronic Diabetes	**PDAC approved on 6/29/2023:** E0784 + E2102 ***OR*** E0784 + E2102 + E0607
Miscellaneous Diabetes Management Systems		
mySentry	Medtronic Diabetes	**PDAC decision on 1/1/2014:** A9279
Sleep Sentry	Diabetes Sentry™	**PDAC decision on 3/10/2008:** A9280

HCPCS Codes A9276-A9278

Prior to February 28, 2022, non-therapeutic (adjunctive) CGMs were reported with HCPCS codes A9276-A9278 and these codes were non-covered by Medicare. *(Noridian* Noncovered Items*)* These codes were also assigned a Status Indicator of "N," which is defined as "Non-covered Services." However, with the change in coverage for non-therapeutic CGMs in February 2022, Medicare created new HCPCS codes for newly Medicare covered devices (E2102 and A4238 noted above) and made the existing codes A9276-A9278 invalid for Medicare use by changing the status indicator of these codes to an "I." as of January 1, 2023, codes A9276-A9278 were once again made valid for Medicare use, but continue to represent non-covered CGM systems, as indicated by the reassignment of the Status Indicator "N" to these codes.

Please note, while some non-therapeutic (adjunctive) CGMs may now be eligible for coverage under Medicare, not all CGM systems will meet Medicare's general statutory DME requirements. Therefore, proper coding for the CGM system provided is critical for appropriate claim adjudication, reimbursement, and benefit application.

While there are no devices currently on the United States market which function as stand-alone adjunctive CGM devices, current technology for adjunctive CGM devices operates in conjunction with an insulin pump.[4] (See "Policy Guidelines" above for more information about current technologies.)

Integrated Insulin Infusion Pumps with CGM Sensing Capabilities

In January 2020, two new HCPCS codes E0787 and A4226 were developed to represent insulin infusion pumps with integrated CGM sensing capabilities and their related accessories (e.g., T:SLIM X2 insulin pump which integrates with the Dexcom CGM). However, effective September 15, 2020, following a review of public input, Medicare determined to make these HCPCS codes invalid for Medicare claims submission.[2] Instead, other codes would be used to report for these systems, retroactively to January 2020.

For dates of service on or after April 1, 2022, suppliers must report both E0784 and E2102 to describe the rental of an insulin pump with integrated adjunctive CGM receiver functionality.[3] Coverage for E2102 (or E1399 for dates of service between February 28, 2022 and March 31, 2022), is only available for the CGM receiver function of a rented insulin infusion pump if the beneficiary does not already own a CGM receiver of any kind (either adjunctive or non-adjunctive) that is less than five years old **and** the beneficiary does not already own an insulin pump of any kind that is less than five years old.[3]

Frequency Limitations

This list is not all-inclusive. Additional frequency and utilization limitations for specific devices and products can be found in the associated LCAs noted above.

Based on HCPCS code descriptions:

- HCPCS A4224: A single unit of service equals a one-**week** supply.
- HCPCS A4238/A4239: Each code represents a one-**month** supply.

Reasonable billing practices do **not** allow a cumulative total of more units than the code descriptor would designate (e.g., more than 12 units of HCPCS codes A4238 or A4239 over the course of 1-year or 12-month period would not be appropriate billing). The cumulative provision of any supplies in excess of the "per week" or "per month" designation found in the HCPCS code descriptor may be subject to review.

Consistent with Medicare billing rules, no more than a 3-month (90-day) quantity of any supply should be dispensed at one time.

Replacement Requests

Replacement of CGMs and Insulin Pumps

The definition of replacement can be found in the Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.2.C. – Replacement, and refers to the provision of an identical or nearly identical item.

Replacement can be due to the following scenarios:

- **Irreparable *damage*** refers to a specific accident or to a natural disaster (e.g., fire, flood).
- **Irreparable *wear*** refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified.

Replacement of CGMs/insulin pumps ***prior to*** the 5-year reasonable useful lifetime (RUL) period being reached:

Replacement due to **irreparable *wear***:

- Medicare expects *rented* equipment to remain in good working order for the entire RUL of the equipment. Therefore, if the equipment does not last for the entire 5-year RUL, the supplier must replace the equipment at no charge.
- For member-owned equipment, coverage for replacement equipment is not allowed prior to the 5-year RUL for irreparable ***wear*** per Medicare statute.

Replacement due to **change in patient medical condition**:

- Replacement of rented or member-owned equipment may be warranted if:

- The current item(s) can no longer meet the patient's therapeutic medical needs; **and**
- It is the least costly option to replace the equipment in order to meet the patient's medical needs (rather than repair or reconfigure with available options).

Replacement of CGMs/insulin pumps ***after*** the 5-year RUL period is reached due to irreparable *wear* ***OR*** replacement ***at any time*** due to *theft, loss,* or irreparable *damage*:

- If the 5-year RUL of the equipment is reached, replacement must still be medically reasonable and necessary:
    - The member must be regularly using the equipment as prescribed; and,
    - The equipment continues to provide the needed therapeutic benefit.
        - For irreparably *worn* devices, documentation must support the current device no longer meets the therapeutic medical needs of the member and cannot be repaired to a state where it can provide the needed therapeutic benefit (e.g., it is not cost effective to repair the current device).
            - If an item is still under manufacturer warranty and can be repaired, requests for replacement with a new device will be denied.
        - For lost, stolen, or irreparably *damaged* devices, documentation of the specific incident of irreparable damage or a written explanation regarding the loss (e.g., details around circumstances of the loss, a police report for stolen items, etc.).

Replacement of Supplies

Supplies necessary to achieve the therapeutic benefit of the device or to assure the proper functioning of a medically necessary device are also covered. This includes replacement of supplies that are consumable, as well as batteries when no longer functional. Because these items generally require replacement on a frequent basis, they are not subject to the same requirements as other DME replacements (i.e., the 5-year RUL rule will not likely apply); however, utilization may be subject to audit and quantity limits may apply, as found in LCDs or LCAs. Please review the LCDs and LCAs above for any potential frequency limitations on replacement supplies.

Disposable Insulin Pumps

Disposable insulin pumps (HCPCS code A9274) do not meet the definition of "durable medical equipment" and thus, are not covered under the DME benefit. However, they may be covered under the Part D Medicare benefit. Therefore, any requests for disposable insulin pumps in Medicare members must go through Pharmacy review.

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 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

HCPCS Codes S1030 and S1031

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[5], indicates HCPCS codes S1030 and S1031 have been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, all S-codes codes, including S1030 and S1031, are not recognized as valid codes for claim submission as indicated in the relevant Company Coding Policy *(HCPCS S-Codes and H-Codes,* 22.0*).* Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

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
	95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording
	95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health

		care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
	95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report
HCPCS	A4224	Supplies for maintenance of insulin infusion catheter, per week
	A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
	A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week *(Effective September 15, 2020, this code is invalid for Medicare claims submission)*
	A4230	Infusion set for external insulin pump, non needle cannula type
	A4231	Infusion set for external insulin pump, needle type
	A4232	Syringe with needle for external insulin pump, sterile, 3 cc
	A4238	Supply allowance for adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
	A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
	A9270	Non-covered item or service
	A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with non-durable medical equipment interstitial continuous glucose monitoring system, one unit = 1 day supply *(Effective April 1, 2022, this code is invalid for Medicare claim submission. Prior to April 1, 2022, this code was not a covered Medicare benefit.)*
	A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system *(Effective April 1, 2022, this code is invalid for Medicare claim submission. Prior to April 1, 2022, this code was not a covered Medicare benefit.)*
	A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system *(Effective April 1, 2022, this code is invalid for Medicare claim submission. Prior to April 1, 2022, this code was not a covered Medicare benefit.)*
	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.)
	E0784	External ambulatory infusion pump, insulin
	E0786	Implantable programmable infusion pump, replacement (excludes implantable intraspinal catheter)
	E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing *(Effective September 15, 2020, this code is invalid for Medicare claims submission)*
	E1399	Durable medical equipment, miscellaneous
	E2102	Adjunctive continuous glucose monitor or receiver
	E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
	~~G0564~~	**CODE TERMED 3/31/2025** ~~Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training~~

	~~G0565~~	**CODE TERMED 3/31/2025** ~~Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation~~
	J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
	K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
	K0602	Replacement battery for external infusion pump owned by patient, silver oxide, 3 volt, each
	K0603	Replacement battery for external infusion pump owned by patient, alkaline, 1.5 volt, each
	K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each
	K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each
	S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code) *(CMS-assigned Status "I" code – See above billing guidelines)*
	S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code) *(CMS-assigned Status "I" code – See above billing guidelines)*

***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. Federal Register CMS-1738-F/CMS-1687-F/CMS-5531-F; Available at: https://www.federalregister.gov/documents/2021/12/28/2021-27763/medicare-program-durable-medical-equipment-prosthetics-orthotics-and-supplies-dmepos-policy-issues. Accessed 2/4/2025.
2. PDAC web page for *Insulin Infusion Pumps with Integrated Continuous Glucose Sensing Capabilities and Related Accessories/Supplies – Codes E0787 and A4226 – Correct Coding*; Last updated: 07/21/2020; Available at: https://www.dmepdac.com/palmetto/PDACv2.nsf/DID/IHF8MMGPIO. Accessed 2/4/2025.

3. PDAC web page for the Joint DME MAC Article, *Continuous Glucose Monitors – Correct Coding and Billing*; Last updated: 03/21/2022; Available at: https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/V6IQOPA73R~Articles%20and%20Publications~Advisory%20Articles. Accessed 2/4/2025.
4. Federal Register. https://public-inspection.federalregister.gov/2024-25382.pdf. Accessed 2/4/2025,
5. 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 2/4/2025.

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.