

Medicare Medical Policy

Advanced 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, Providence Plan Partners, and Ayin Health Solutions 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:

- Prior to May 11, 2023, there were temporary provisions in place for this Medicare medical policy during the COVID-19 public health emergency. See [Policy Guidelines](#) below for information regarding these emergency provisions.
- 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
<ul style="list-style-type: none"> • Omnipod Dash • Omnipod 5 ACE Pump • V-Go Wearable Insulin Delivery 	<ul style="list-style-type: none"> • Freestyle Libre • Dexcom G5/G6

Service	Medicare Guidelines
<i>Continuous Glucose Monitors (CGMs) and related supplies; Therapeutic or non-adjunctive (HCPCS codes E2103 and A4239) and Non-Therapeutic or adjunctive (HCPCS codes E2102 and A4238)</i>	Local Coverage Determination (LCD): Glucose Monitors Devices (L33822)
<i><u>External Insulin Infusion Pump</u> (HCPCS codes E0784)</i>	LCD: External Infusion Pumps (L33794) (Note: see criterion IV.)
<i><u>Integrated Insulin Infusion Pumps with CGM Sensing Capabilities</u></i>	<ul style="list-style-type: none"> • LCD: External Infusion Pumps (L33794) • LCD: Glucose Monitors Devices (L33822)

	<p>Notes:</p> <ul style="list-style-type: none"> 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. <p>See “Billing Guidelines” below for more information on these integrated devices and how to code them for claim submission.</p>
CGM devices <u>without</u> a standalone receiver (e.g., system relies solely on a software application [app] added to a smart device with no integration with a pump)	LCD: Glucose Monitors Devices (L33822)
<u>Implantable</u> Insulin Infusion Pumps	National Coverage Determination (NCD) for Infusion Pumps (280.14) (See Criterion C.2.)
<u>Implantable</u> Continuous Glucose Monitors (I-CGM; CPT codes 0446T, 0447T, or 0448T)	Local Coverage Determination (LCD): Implantable Continuous Glucose Monitors (I-CGM) (L38659)

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

- [Diabetes: 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

NEED AND DURATION OF EMERGENCY PROVISIONS

- Need for the temporary Provisions:** COVID-19 public health emergency

2. Documents or source relied upon:

- a. Rural Crosswalk: CMS Flexibilities to Fight COVID-19:
<https://www.cms.gov/files/document/omh-rural-crosswalk-5-21-21.pdf>
- b. Noridian Article [CMS Issues Interim Final Rules with Comment \(CMS-1744-IFC & CMS-5531-IFC\) – COVID-19 Public Health Emergency – Revised](#); [Last updated 07/14/2021]
- c. CMS Final Rule: CMS-5531-IFC for Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program
- d. CMS Final Rule: CMS-1744-IFC for Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency
- e. CMS [COVID-19 Frequently Asked Questions \(FAQs\) on Medicare Fee-for-Service \(FFS\) Billing](#) document [Last updated 11/17/2021]

3. Initial Effective Date: 3/1/2020

4. Re-review dates: 11/30/2020; 2/3/2021; 3/31/2021; 6/1/2021; 12/8/2021; 7/20/2022; 10/4/2022; 12/16/2022; 1/30/2023

5. Termination Date: 5/11/2023

6. Reassessment Date determined at Companies sole discretion: 5/10/2023 or sooner if regulations or clinical practice guidelines change.

POLICY ADDENDUM

COVID-19 Public Health Emergency

Since March 2020, Medicare has released various final rules on the CMS response to the COVID-19 public health emergency (PHE). Some of these final rules apply to enforcement of certain requirements for select durable medical equipment (DME) and supplies (e.g., face-to-face or in-person encounters or provider specialty requirements when required by NCD/LCD, etc.).

“For the duration of this PHE for the COVID-19 PHE, it is in the best interest of patients, health care professionals and suppliers to limit face-to-face encounters and avoid exposure of vulnerable Medicare beneficiaries to COVID-19. Therefore, on an interim basis, we are finalizing that to the extent an NCD or LCD (including policy articles) would otherwise require a face-to-face or in-person encounter for evaluations, assessments, certifications or other implied face-to-face services, those requirements would not apply during the COVID-19 PHE.”¹

Thus, telehealth (telemedicine) visits would satisfy any face-to-face or in-person requirements when noted in an NCD, LCD, or LCA.

“Effective for claims with dates of service on or after March 1, 2020 and for the duration of this COVID-19 PHE, clinical indications for coverage found in respiratory, infusion pump, and therapeutic continuous glucose monitor NCDs or LCDs will not be enforced. These NCDs and LCDs include:

- Home Oxygen (NCD 240.2)
- **Infusion Pumps (NCD 280.14)**
- Continuous Positive Airway Pressure for Obstructive Sleep Apnea (NCD 240.4)

- *Intrapulmonary Percussive Ventilator (NCD 240.5)*
- *Durable Medical Equipment Reference List (NCD 280.1) – Only clinical indications for ventilators are not enforced*
- *Oxygen and Oxygen Equipment (L33797)*
- *Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea (L33718)*
- *Oral Appliances for the Treatment of Obstructive Sleep Apnea (L33611)*
- *Respiratory Assist Devices (L33800)*
- *Mechanical In-exsufflation Devices (L33795)*
- *High Frequency Chest Wall Oscillation (L33785)*
- *Nebulizers (L33370)*
- *Suction Pumps (L33612) – Only clinical indications for respiratory suction pumps (E0600) are not enforced*
- ***Glucose Monitors (L33822) – Only clinical indications for Therapeutic Continuous Glucose Monitors (CGM) are not enforced***
- ***External Infusion Pumps (L33794)***¹

Treating practitioners and suppliers must still:

- Provide a standard written order (SWO) for all items.
- Ensure that the items or services are reasonable and necessary;
- Continue documenting the medical necessity for all services and the medical record must be sufficient to support payment for the services billed (i.e., the services were actually provided, were provided at the level billed, and were medically necessary);
- Make documentation available, upon request.¹

While prior authorization and review will not be required for the items addressed by this medical policy, the [CMS-5531-IFC](#) clarifies that the lack of enforcement of certain elements of NCDs and LCDs does **not** mean medical necessity requirements for items and services are waived during this PHE. This final rule serves to “*remind physicians, practitioners and suppliers that most items and services must be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member to be paid under Part A or Part B of Title XVIII. Physicians, practitioners, and suppliers are required to continue documenting the medical necessity for all services. Accordingly, the medical record must be sufficient to support payment for the services billed...*”

BACKGROUND

Under Medicare, continuous glucose monitors (CGMs) include both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs. Therefore, the terms “therapeutic” and “non-adjunctive” may be used interchangeably, as well as the terms “non-therapeutic” and “adjunctive.”

“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)

Prior to February 28, 2022, Medicare did not provide coverage for “non-therapeutic” (adjunctive) CGM products. “On February 28, 2022, CMS determined that both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs may be classified as DME.” (LCD L33822)

Some types of products may be covered or non-covered, based on how they are used. 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.² 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.

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: Glucose Monitor – Policy Article ([A52464](#))
- LCA: Billing and Coding: Implantable Continuous Glucose Monitors (I-CGM) ([A58138](#))
- LCA: External Infusion Pumps ([A52507](#))

ADDITIONAL NOTES

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.³

Adjunctive CGMs

Adjunctive CGMs are CGM systems which do not replace standard blood glucose monitors for treatment decisions. These are also known as “non-therapeutic” CGM systems. For dates of service effective February 28, 2022, adjunctive CGMs and related supplies and accessories are eligible for coverage under the Part B DME benefit category when the system meets Medicare’s durable medical equipment (DME) definition.⁴

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.)

- **For February 28, 2022 and March 31, 2022:** Use HCPCS code E1399 and A9999 to report for these systems and related supplies and accessories, respectively.
- **As of April 1, 2022:** Use HCPCS codes E2102 and A4238 for adjunctive CGMs and related supplies and accessories, respectively.⁴

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.⁴

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.⁴

HCPCS Codes A9276-A9278

Prior to February 28, 2022, non-therapeutic 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.”

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.

Frequency Limitations

Based on HCPCS code descriptions, HCPCS codes A4224 and A4225 will not be reimbursed more than 52 times per calendar year.

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.

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 L58138 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

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
	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 (<i>Effective September 15, 2020, this code is invalid for Medicare claims submission</i>)
	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 (<i>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.</i>)
A9277	Transmitter; external, for use with non-durable medical equipment interstitial continuous glucose monitoring system (<i>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.</i>)
A9278	Receiver (monitor); external, for use with non-durable medical equipment interstitial continuous glucose monitoring system (<i>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.</i>)
A9999	Miscellaneous DME supply or accessory, not otherwise specified
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing (<i>Effective September 15, 2020, this code is invalid for Medicare claims submission</i>)
E1399	Durable medical equipment, miscellaneous
E2102	Adjunctive continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
G0308	TERMED 12/31/2022 Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
G0309	TERMED 12/31/2022 Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation
J1817	Insulin for administration through DME (i.e., insulin pump) per 50 units
K0553	TERMED 12/31/2022 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 unit of service = 1 month's supply
K0554	TERMED 12/31/2022 Receiver (Monitor), dedicated, for use with therapeutic continuous glucose monitor system
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

***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. Noridian web page for the Joint DME MAC Article, *CMS Issues Interim Final Rules with Comment (CMS-1744-IFC & CMS-5531-IFC) – COVID-19 Public Health Emergency – Revised*; Last updated 07/14/2021; Available at: <https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2020/cms-issues-interim-final-rules-with-comment-cms-1744-ifc-cms-5531-ifc-covid-19-public-health-emergency-revised3> [Last cited 02/08/2022]
2. Federal Register CMS-1738-F/CMS1687-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> [last cited 3/24/2022]
3. Noridian web page for the Joint DME MAC Article, *Insulin Infusion Pumps with Integrated Continuous Glucose Sensing Capabilities and Related Accessories/Supplies – Codes E0787 and A4226 – Correct Coding*; Last updated: 07/20/2020; Available at: <https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2020/insulin-infusion-pumps-with-integrated-continuous-glucose-sensing-capabilities-and-related-accessories-supplies-codes-e0787-and-a4226-correct-coding> [Last cited 02/08/2022]
4. PDAC web page for the Joint DME MAC Article, *Continuous Glucose Monitors – Correct Coding and Billing*; Last updated: 03/01/2022; Available at: <https://dmepdac.com/palmetto/PDACv2.nsf/DIDC/V6IQOPA73R~Articles%20and%20Publications~Advisory%20Articles>

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
1/2023	Q1 2023 code updates (converted to new format 2/2023)