Medicare Medical Policy

Advanced Diabetes Management Technology

MEDICARE MEDICAL POLICY NUMBER: 25

Effective Date: 7/1/2023

Last Review Date: 6/2023

Next Annual Review: 3/2024

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:

- 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**
• OmnipodV-Go	• Freestyle Libre • Dexcom

Service	Medicare Guidelines
Continuous Glucose Monitors (CGMs) and related supplies • ***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)*	Local Coverage Determination (LCD): Glucose Monitors Devices (L33822)
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 (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)
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: • 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.

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

1. **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). 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)*

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.[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.

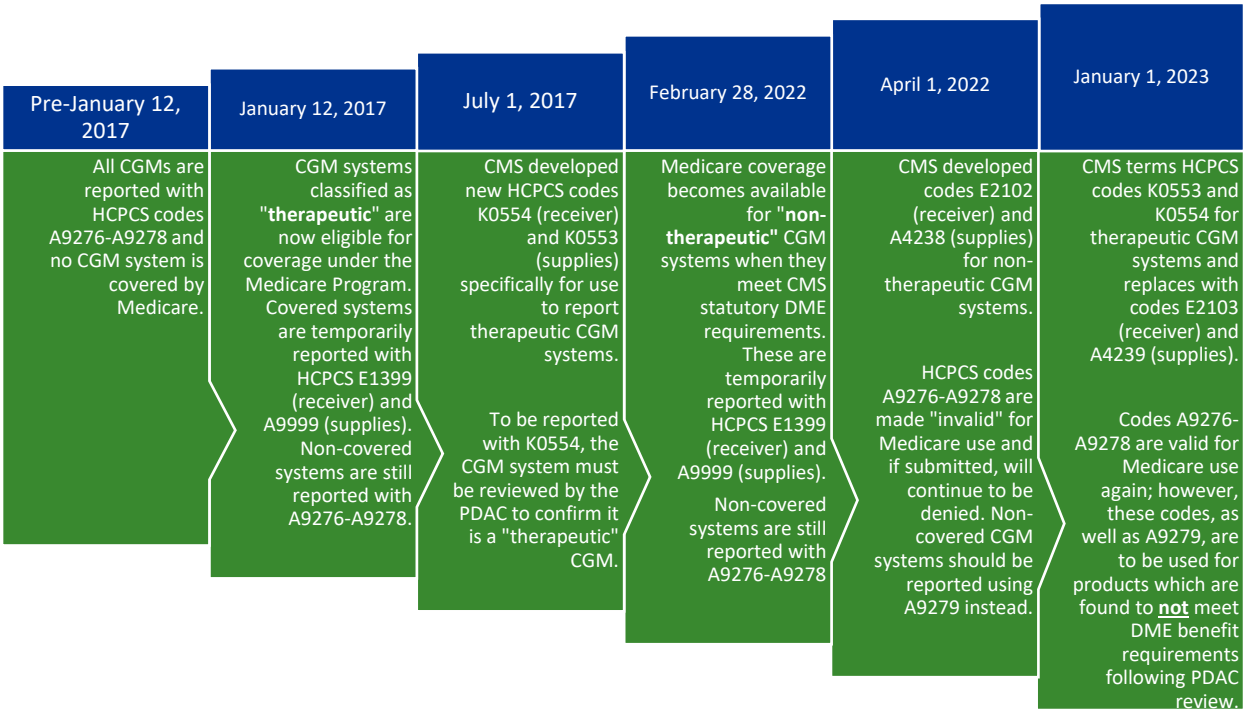
REGULATORY STATUS

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

HISTORY OF MEDICARE CGM COVERAGE AND ASSOCIATED 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)

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 and benefit application.**

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.

Product/Device Name	Manufacturer	HCPCS Code(s)
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)
G5 Mobile CGM Touchscreen Receiver	DexCom	**1/1/2023:** E2103 (Receiver) and A4239 (Supplies) **½/2018-12/31/2022:** 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)
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)*

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

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.[3] 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.[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]

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 codes A4224 will not be reimbursed more than 52 times per calendar year. In addition, a cumulative total of 12 requests for supply allowance for CGMs (HCPCS codes A4238 or A4239) are eligible for reimbursement per calendar year.

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 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

HCPCS Codes S1030 and S1031

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[1], 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.

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 *(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
	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
	~~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~~
	J1811	Insulin (Fiasp) for administration through DME (i.e., insulin pump) per 50 units
	J1813	Insulin (Lyumjev) for administration through DME (i.e., insulin pump) per 50 units
	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
	S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code)

	S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data, use CPT code)

***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 RETIRED 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 12/22/2022; Available at: https://med.noridianmedicare.com/web/jadme/policies/dmd-articles/2022/cms-issues-interim-final-rules-with-comment-cms-1744-ifc-cms-5531-ifc-covid-19-public-health-emergency-revised2. Accessed 01/30/2023.
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. Accessed 01/30/2023.
3. 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 01/30/2023.
4. 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 01/30/2023.

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 and Q3 2023 code updates; no change to criteria