Medtronic

Medicare Durable Medical Equipment – Glucose Monitors

Guardian™ 4 Sensor System Coding and Medicare Coverage

The Medicare program pays for continuous glucose monitors (CGM), blood glucose monitors (BGM), as well as insulin pumps, also referred to as automatic insulin delivery (AID) systems and related supplies. Suppliers bill by Healthcare Common Procedure Coding System (HCPCS) codes to signify the equipment and supplies provided.

HCPCS Codes

HCPCS Code	Description
E0607	Home blood glucose monitor
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103†	Non-adjunctive, non-implanted continuous glucose monitor or receiver
A4238	Supply allowance for adjunctive, non-implanted 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
A4245	Alcohol wipes, per box
A4247	Betadine or iodine swabs / wipes, per box
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4256	Normal, low and high calibrator solution / chips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100

†E2103 includes E0607, A4245, A4247, A4253 and A4259 (home Blood Glucose Monitor and related supplies).

Local Coverage Determination (LCD) – Glucose Monitors

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. In addition to the "reasonable and necessary" criteria outlined here, please consult your DME MAC website for applicable supplier manual information and any related coverage and payment articles. Patient medical record must fully document that patient meets all coverage requirements per Medicare policy.

Blood Glucose Monitors (BGM)

Coverage of home blood glucose monitors (non-disposable) and supplies (lancets (A4259), blood glucose reagent strips (A4253), glucose control solutions (A4256) and spring powered devices for lancets (A4258)) requires that the patient meets both criteria:

1. Has an ICD-10-CM code diagnosis of diabetes; and,
2. The treating practitioner has concluded that the patient / caregiver has sufficient training using the particular device prescribed as evidenced by providing a prescription for the appropriate supplies and frequency of blood glucose testing.

If both criteria are not met the device and related supplies will not be covered.

Test Strips (A4253) and Lancets (A4259)

Treated with Insulin (?)	A4253 per 3 months	A4259 per 3 months	Additional Criteria
No	100	100	None
Yes	300	300	None
No / Yes	>100/>300	>100/>300	Must document in medical record: A. Criteria 1 & 2 above; *and,* B. In-person or telehealth visit with treating practitioner within 6 months of order to evaluate glucose control and need for excess strips; *and,* C. Treating practitioner must verify adherence to the high utilization testing regimen prior to dispensing

For patients with visual impairment and/or manual dexterity impairment, glucose monitors with special features (E2100, E2101) may be covered. Consult the Medicare LCD for Glucose Monitors for more information.

Continuous Glucose Monitors (CGMs)

Definitions:

- **Adjunctive CGM (E2102):** Requires verification of glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions; devices that solely display results on a smartphone 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
- **Non-adjunctive CGM (E2103):** Can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results; devices that solely display results on a smartphone 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

Coverage of a CGM and related supplies requires that the patient meet the following criteria:

1. Has an ICD-10-CM code diagnosis of diabetes; and,
2. The treating practitioner has concluded that the patient / caregiver has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
3. The CGM is prescribed in accordance with its FDA indications for use; and,
4. To improve glycemic control, the patient meets at least one of the criteria below:
    A. Patient is insulin-treated; or,
    B. Patient has a history of problematic hypoglycemia with documentation of at least one of the following:
        - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
        - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or telehealth visit with the patient to evaluate their diabetes control and to determine that criteria (1)-(4) above are met.

If any of the coverage criteria are not met, the CGM and related supplies will not be covered.

Continuing coverage of CGM:

Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person or telehealth visit with the patient to document adherence to their CGM regimen and diabetes treatment plan.

- Supplies (A4238) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the patient meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump located in the External Infusion Pump LCD.
- Non-adjunctive CGM replace standard home BGMs and related supplies (HCPCS A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). Claims for a BGM and related supplies, billed in addition to a non-adjunctive CGM device (E2103) and associated supplies (A4239), will be denied.
- Adjunctive CGMs do not replace home BGM. A4238 does not include a BGM and related supplies and may be billed separately.

Devices using E2102 or E2103 are required to be verified by the Medicare DME Pricing, Data Analysis and Coding (PDAC) unit prior to billing under these codes. See DME PDAC for more information.

Standard Written Order (SWO):

A SWO must be communicated to the supplier prior to a claim being submitted. A written order prior to delivery (WOPD) is required for the BGM and / or the CGM which requires that a signed SWO must be received by the supplier prior to delivery. The WOPD for the BGM / CGM must be received prior to the billing of any related supplies.

Refill Requirements:

- Refills are based on the prospective, and not retrospective need of the patient.
- Patient must be contacted no sooner than 30 days prior to the expected exhaustion of supplies to verify the need for additional supplies. Delivery of refills cannot occur sooner than 10 days prior to exhaustion of supplies.
- No more than a 3-month quantity of BGM testing supplies can be dispensed at a time
- *Refill requirements do not apply to codes A4238 or A4239*. The supply allowance (code A4238 or A4239) is a monthly allowance that may be billed up to a maximum of three (3) units of service (UOS) per 90 days of time. No more than a ninety (90) day supply may be dispensed at a time.

Modifiers Used for Billing Medicare:

Submission of claims to Medicare may require the use of modifiers. See page 26 of this guide and consult the DMEPOS supplier manual and Glucose Monitor LCD Articles for more information.

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Medicare Durable Medical Equipment – Insulin Pump

MiniMed™ 780G Coding and Medicare Coverage

The Medicare program pays for continuous glucose monitors (CGM) as well as blood glucose monitors (BGM), insulin pumps, also referred to as automatic insulin delivery (AID) systems and related supplies. Suppliers bill by Healthcare Common Procedure Coding System (HCPCS) codes to signify the equipment and supplies provided.

HCPCS Codes

HCPCS Code	Description
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
E0784	External ambulatory infusion pump, insulin
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each
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

Medicare Part B Clinical Coverage Criteria

Local Coverage Determination (LCD) – External Infusion Pumps

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. In addition to the "reasonable and necessary" criteria outlined here, please consult your DME MAC website for applicable supplier manual information and any related coverage and payment articles.

Patient medical record must fully document that patient meets all coverage requirements per Medicare policy.

Insulin Pumps

Administration of continuous subcutaneous insulin for the treatment of diabetes as evidenced by a qualifying ICD-10-CM diagnosis code is covered if criterion A or B is met and if criterion C or D is met:

A. C-peptide testing requirement – must meet criterion 1 or 2 and criterion 3:
    1. C-peptide level is <= 110 percent of the lower limit of normal of the laboratory's measurement method.
    2. For patients with renal insufficiency and a creatinine clearance (actual or calculated from age, weight, and serum creatinine) <= 50 ml/minute, a fasting C-peptide level is <= 200 percent of the lower limit of normal of the laboratory's measurement method.
    3. A fasting blood sugar obtained at the same time as the C-peptide level is <= 225 mg/dl.
B. Beta cell autoantibody test is positive.
C. Patient has completed a comprehensive diabetes education program, has been on a program of multiple daily injections of insulin (i.e., at least 3 injections per day) with frequent self-adjustments of insulin dose for at least 6 months prior to initiation of the insulin pump, and has documented frequency of glucose self-testing an average of at least 4 times per day during the 2 months prior to initiation of the insulin pump, and meets one or more of the following criteria (1 - 5) while on the multiple injection regimen:
    1. Glycosylated hemoglobin level (HbA1C) > 7 percent
    2. History of recurring hypoglycemia
    3. Wide fluctuations in blood glucose before mealtime
    4. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL
    5. History of severe glycemic excursions
D. The patient has been on an external insulin infusion pump prior to enrollment in Medicare and has documented frequency of glucose self-testing an average of at least 4 times per day during the month prior to Medicare enrollment.

If criterion A or B is not met, and/or criterion C or D is not met, the pump and related supplies, and insulin will be denied as not reasonable and necessary.

Continued Coverage:

- Continued coverage of an external insulin pump (E0784) and supplies requires that the beneficiary be seen and evaluated by the treating practitioner at least every 3 months.
- In addition, the external insulin infusion pump must be ordered and follow-up care rendered by a practitioner who manages multiple beneficiaries on continuous subcutaneous insulin infusion therapy and who works closely with a team including nurses, diabetic educators, and dieticians who are knowledgeable in the use of continuous subcutaneous insulin infusion therapy.

Insulin Pumps and CGM Receivers

Non-Adjunctive Receiver	Adjunctive Receiver
The combination of E0784 plus E2103 is used to describe external ambulatory insulin infusion pumps that incorporate dose rate adjustment using non-adjunctive continuous glucose sensing. Coverage for this HCPCS code combination is only met if the patient meets all of the coverage criteria for insulin pumps and all criteria for CGMs as outlined in the respective Medicare LCDs.	The combination of E0784 plus E2102 is used to describe external ambulatory insulin infusion pumps with integrated adjunctive continuous glucose monitor receiver functionality. Coverage for this HCPCS code combination is only met if the patient meets all of the coverage criteria for insulin pumps and all criteria for CGMs as outlined in the respective Medicare LCDs.

Supplies and Drugs:

- Supplies used with an insulin pump (A4225) are covered when the insulin pump is covered. A4224 and A4225 are covered when used with an insulin pump (A0784)
- Drugs may only be billed by the licensed entity who meets all regulatory requirements and is dispensing the drugs to the patient

Standard Written Order (SWO):

A SWO must be communicated to the supplier prior to a claim being submitted. A written order prior to delivery (WOPD) is required for the insulin pump which requires that a signed SWO must be received by the supplier prior to delivery. The WOPD for the insulin pump must be received prior to the billing of any related supplies.

Refill Requirements:

- Refills are based on the prospective, and not retrospective need of the patient.
- Patient must be contacted no sooner than 30 days prior to the expected exhaustion of supplies to verify the need for additional supplies. Delivery of refills cannot occur sooner than 10 days prior to exhaustion of supplies.
- No more than a 3-month quantity of supplies can be dispensed at a time

Modifiers Used for Billing Medicare - Insulin:

- For a 1 month or less supply of insulin, JK modifier must be added to codes J1811, J1813 or J1817
- For a 3-month supply of insulin, JL modifier must be added to codes J1811, J1813 or J1817

Submission of claims to Medicare may require additional use of modifiers. Consult the DMEPOS supplier manual and External Infusion Pump LCD Articles for more information.

2025 Medicare DMEPOS Fee Schedule by HCPCS Code

Diabetes devices and related supplies

This chart contains the 2025 Medicare national average payment amounts by HCPCS code. For payment amounts specific to a geography, please visit the CMS website at DMEPOS Fee Schedule Files. Commercial insurance payment amounts will vary by carrier and any direct contracts.

The information below identifies MiniMed 780G Insulin Pump and Guardian 4 Sensor System (CGM) to help illustrate coding application by product. The information is also applicable to earlier iterations of Medtronic Diabetes products by category (e.g., Insulin Pump and Continuous Glucose Monitors).

Medicare National Payment Rate

HCPCS Code	Description	Modifier	2025 NPR
A4224	Supplies for maintenance of insulin infusion catheter, per week.		$25.34
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each.		$3.39
A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service.	KF	$275.21
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service.	KF	$267.92 $311.74
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips.	NU	$8.32
A4256	Normal, low and high calibrator solution / chips.		$3.38
A4258	Spring-powered device for lancet, each.		$2.12
A4259	Lancets, per box of 100.		$1.42
E0607	Home blood glucose monitor.	NU RR	$93.87 $9.38
E0784	External ambulatory infusion pump, insulin.	RR	$543.94
E2102†	Adjunctive, non-implanted continuous glucose monitor or receiver.	NU, KF RR, KF	$223.27 $22.33

†CGMs (E2102 and E2103) and related supplies (A4238 and A4239) which are classified by the Food & Drug Administration as Class III devices must include the KF modifier.

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HCPCS Code	Description	Modifier	2025 NPR
E2103†	Non-adjunctive, non-implanted continuous glucose monitor or receiver.	NU RR NU, KF RR, KF	$285.67 $28.57 $317.14 $31.71
K0601	Replacement battery for external infusion pump owned by patient, silver oxide, 1.5 volt, each.		$1.53
J1811*	Insulin (fiasp) for administration through DME (i.e., insulin pump) per 50 units.		$7.900
J1813*	Insulin (lyumjev) for administration through DME (i.e., insulin pump) per 50 units.		$15.476
S1034^	Artificial pancreas device system (e.g. low glucose suspend feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices		N/A
S1035^	Sensor; invasive (e.g. subcutaneous), disposable, for use with artificial pancreas device system		N/A
S1036^	Transmitter; external, for use with artificial pancreas device system		N/A
S1037^	Receiver (monitor); external, for use with artificial pancreas device system		N/A

* Patient co-pay for insulin not to exceed $35 per month
†CGMs (E2102 and E2103) and related supplies (A4238 and A4239) which are classified by the Food & Drug Administration as Class III devices must include the KF modifier.
^"S" codes non-covered by Medicare; may be utilized by non-Medicare payers, consult specific payers for more information.

Modifiers

Modifier	Description
NU	New Durable Medical Equipment Purchase
RR	Rental (Use the 'RR' Modifier when DME is to be rented)
KF	Item Designated by FDA as Class III Devices
KX	Requirements specified in the Medical Policy have been met
JK	One month supply or less of drug or biological
JL	Three-month supply of drug or biological

Note: Additional modifiers may apply per individual coverage policy.

The Automated Insulin Delivery (AID) & Continuous Glucose Monitor (CGM) Durable Medical Equipment, Prosthetic Devices, Prosthetics, Orthotics, & Supplies (DMEPOS) Reimbursement Guide has been developed as an introductory reference guide to coding, coverage and payment for professional services providers and durable medical equipment (DME) suppliers in the care of patients with diabetes. The Guide outlines codes commonly used for billing in each setting; national average payment rates for physicians and DME suppliers; and coverage criteria under the Medicare Part B DMEPOS benefit.

This Guide should not be viewed as inclusive of all coding, coverage and payment information that may be needed. It does not replace advice from your coding, billing, compliance, legal, or other applicable departments. The responsibility for correctness lies with the provider or supplier of services. Documentation in the medical record must support the coding used and billing submitted to the payer(s). Payer coverage guidelines may vary from Medicare criteria therefore, each payer should be individually consulted for specific requirements.

Disclaimer

Medtronic provides this information for your convenience only. It does not constitute legal advice or a recommendation regarding clinical practice. Information provided is gathered from third-party sources and is subject to change without notice due to frequently changing laws, rules, and regulations. The provider has the responsibility to determine medical necessity and to submit appropriate codes and charges for care provided. Medtronic makes no guarantee that the use of this information will prevent differences of opinion or disputes with Medicare or other payers as to the correct form of billing or the amount that will be paid to providers of service. Please contact your Medicare contractor, other payers, reimbursement specialists, and/or legal counsel for interpretation of coding, coverage, and payment policies. This document aids with FDA-approved or cleared indications. Where reimbursement is sought for use of a product that may be inconsistent with, or not expressly specified in, the FDA-cleared or approved labeling (e.g., instructions for use, operator's manual, or package insert), consult with your billing advisors or payers on handling such billing issues. Some payers may have policies that make it inappropriate to submit claims for such items or related services.

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