Priority Health

MEDICAL POLICY No. 91466-R10

CONTINUOUS GLUCOSE MONITORING AND INSULIN PUMPS

Effective Date: February 1, 2025

Review Dates: 2/03, 1/04, 7/04, 7/05, 6/06, 6/07, 2/08, 8/08, 8/09, 4/10, 4/11, 4/12, 4/13, 5/14, 5/15, 5/16, 5/17, 5/18, 5/19, 5/20, 5/21, 5/22, 11/22, 11/23, 11/24

Date Of Origin: February 26, 2003

Status: Current

Summary of Changes

Changes:

- Devices which integrate continuous glucose monitors and insulin pumps as an automated insulin delivery system for insulin suspension capability or for suspending and adjusting basal insulin infusion are now considered medically necessary.
- Policy title changed to reflect scope.

Clarifications:

- Clarified section on Medicaid criteria to reflect updates to Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual.
- Moved paragraph discussing details as to how to obtain a medically necessary continuous glucose monitoring device/system to top of policy.

For details as to how to obtain a medically necessary continuous glucose monitoring (CGM) device/system (including transmitter, sensors, and receiver/monitor, with or without a continuous subcutaneous insulin infusion pump), refer to the Priority Health Provider Manual: Continuous glucose monitors. Devices under warranty that require replacement are not a covered benefit.

I. POLICY/CRITERIA

A. Continuous glucose monitoring (CGM) devices/systems (including transmitters, sensors, receivers/monitors; and potentially combined with continuous subcutaneous insulin infusion pumps) may be considered medically necessary as follows:

1. **Commercial**: The following may be considered medically necessary for a commercial member when corresponding InterQual® criteria are met (**CP:Durable Medical Equipment - *Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology***):

   i. Continuous glucose monitoring devices (CGM) (real time [rtCGM] and intermittently scanned [isCGM])
   ii. Continuous subcutaneous insulin infusion (CSII) pumps
   iii. FDA-approved technology devices which integrate CGMs and CSII pumps for sensor-augmented therapy
   iv. FDA-approved technology and devices which integrate CGMs and CSII pumps as an automated insulin delivery system for insulin suspension capability (low glucose suspend) or for suspending and

adjusting basal insulin infusion (hybrid closed-loop, manual control of bolus dosing)

Note: Alternate names for this equipment include:

- Artificial pancreas device system
- Automated insulin delivery system (AID)
- Closed-loop system
- Continuous subcutaneous insulin infusion (CSII) pump
- External insulin infusion pump
- Flash glucose monitor
- Hybrid closed-loop system
- Integrated continuous glucose monitoring system (iCGM)
- Intermittently scanned continuous glucose monitor (isCGM)
- Real time continuous glucose monitor (rtCGM)
- Sensor-augmented insulin pump (SAP)

2. **Medicaid**: Diabetic equipment and related supplies may be considered medically necessary for a Medicaid member when the criteria specified in the current Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual are met. Relevant sections are as follows:

Coverage Conditions and Requirements:

Diabetic Equipment and Related Supplies:

Blood Glucose Monitoring Equipment and Supplies
Continuous Glucose Monitoring Equipment and Supplies
External Infusion (Insulin) Pump and Supplies

3. **Medicare**: A CGM device/system may be considered medically necessary for a Medicare member when the criteria specified in the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) L33822 Glucose Monitors (CGS Administrators, LLC; Noridian Healthcare Solutions, LLC) are met.

A continuous glucose monitor (GCM) may be integrated into an external insulin infusion pump. Such an integrated CGM system may be considered medically necessary when the member meets both the CGM coverage criteria (specified above) and the coverage criteria for *administration of continuous subcutaneous insulin for the treatment of diabetes mellitus* specified in the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) L33794 External

Infusion Pumps (CGS Administrators, LLC; Noridian Healthcare Solutions, LLC).

Therapeutic/non-adjunctive and non-therapeutic/adjunctive **implantable continuous glucose monitors (I-CGMs)** are considered reasonable and necessary by Medicare when all of the coverage criteria specified in the Centers for Medicare & Medicaid Services (CMS) Local Coverage Determination (LCD) L38686 Implantable Continuous Glucose Monitors (I-CGM) (Wisconsin Physicians Service Insurance Corporation) are met.

B. Other limitations/considerations:

- The mySentry™ Remote Glucose Monitor, a MiniMed accessory, is not a covered benefit.
- Software or hardware required for downloading data to a device, such as a personal computer, smart phone, or tablet, to aid in the self-management of diabetes mellitus is considered not medically necessary.

C. Priority Health will cover 72-hour continuous glucose monitoring for patients with labile blood sugars and the need for intensive short-term monitoring for improving blood glucose control.

II. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, device, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

Note: The need for medical necessity review varies by line of business (Commercial, Medicaid, or Medicare) and benefit. See the Priority Health Provider Manual: Continuous glucose monitors for additional details.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy applies to insured HMO/EPO plans.***
- **POS:** ***This policy applies to insured POS plans.***
- **PPO:** ***This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***

- **ASO:** ***For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

The two common types of diabetes are type 1 and type 2. Type 1 diabetes, known as insulin-dependent diabetes, is a chronic condition in which the pancreas produces little or no insulin. Insulin is a hormone needed to allow sugar (glucose) to enter cells to produce energy. Type 2 diabetes is the most common form of diabetes, in which your body does not use insulin properly.

According to the American Diabetes Association, 34.2 million Americans have diabetes. Of the 34.2 million Americans, 14.3 million are seniors aged 65 and older.

The complications of diabetes mellitus are far less common and less severe in people who have well-controlled blood sugar levels. Acute complications include hypoglycemia, hyperglycemia, diabetic coma, and nonketotic hyperosmolar coma. Chronic hyperglycemia, resulting from poorly controlled diabetes, may result in serious and life-threatening damage, including dysfunction and failure of the eyes, kidneys, nervous system and cardiovascular system.

Continuous glucose monitoring systems (CGMS) are minimally invasive or noninvasive devices that measure glucose levels in interstitial fluid. The devices provide continuous "real-time" readings and data about trends in glucose levels. This may allow people with diabetes to understand the level of their glucose, and to intervene by eating food or taking insulin to prevent glucose levels from going too high or too low. The device is most likely to benefit those patients who have:

- hypoglycemic unawareness, hypoglycemic seizures, or nocturnal hypoglycemia
- diabetes while pregnant or
- not reached optimal HbA1c target despite best efforts by the patient and the treating physician

The components of the CGMS are:
1) Receiver
2) Transmitter
3) Sensor

The general term CGM refers to both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs. 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. On February 28, 2022, CMS determined that both therapeutic/non-adjunctive and non-therapeutic/adjunctive CGMs may be classified as DME.

The American Association of Clinical Endocrinology (AACE) maintains a CGM Device Comparison table within its Guide to Continuous Glucose Monitoring (CGM).

V. CODING AND BILLING

ICD-10 Codes that may apply:

E08.00 – E08.9	Diabetes mellitus due to underlying condition
E09.00 – E09.9	Drug or chemical induced diabetes mellitus
E10.10 – E10.9	Type 1 diabetes mellitus
E11.00 – E11.9	Type 2 diabetes mellitus
E13.00 – E13.9	Other specified diabetes mellitus
O24.011 – O24.93	Diabetes mellitus in pregnancy, childbirth, and the puerperium
O99.810 – O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium
Z46.81	Encounter for fitting and adjustment of insulin pump
Z79.4	Long term (current) use of insulin
Z90.410	Acquired total absence of pancreas
Z90.411	Acquired partial absence of pancreas
Z96.41	Presence of insulin pump (external) (internal)

CPT\HCPCS:

95250 Glucose monitoring for up to 72 hours by continuous recording and storage of glucose values from interstitial tissue fluid via a subcutaneous sensor (includes hook-up, calibration, patient initiation and training, recording, disconnection, downloading with printout of data). *No prior authorization required.*

95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report
A4224	Supplies for maintenance of insulin infusion catheter, per week *(not covered for Medicaid)*
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each *(not covered for Medicaid)*
A4226	Supplies for maintenance of insulin infusion pump with dosage rate adjustment using therapeutic continuous glucose sensing, per week *(not covered for Medicaid)*
A4230	Infusion set for external insulin pump, nonneedle 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, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per 50 tests
A4602	Replacement battery for external infusion pump owned by patient, lithium, 1.5 volt, each *(not covered for Medicaid)*
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories *(May only be covered under member's pharmacy benefit for some plans.)*
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial Continuous glucose monitoring system, 1 unit = 1 day
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system *(Not covered for Medicare or Medicaid)*
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing *(not covered for Medicaid)*
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver
E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge *(not covered for Medicaid)*
K0604	Replacement battery for external infusion pump owned by patient, lithium, 3.6 volt, each *(not covered for Medicaid)*
K0605	Replacement battery for external infusion pump owned by patient, lithium, 4.5 volt, each *(not covered for Medicaid)*
S1034	Artificial pancreas device system (e.g., low glucose suspend [LGS] feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices (payable for Commercial only)
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system (payable for Commercial only)
S1036	Transmitter; external, for use with artificial pancreas device system (payable for Commercial only)

S1037 Receiver (monitor); external, for use with artificial pancreas device system (payable for Commercial only)
S9145 Insulin pump initiation, instruction in initial use of pump (pump not included) (*not separately payable)*

Not covered:
0446T Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training (covered for Medicare)
0447T Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision (covered for Medicare)

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 (covered for Medicare)
G0564 Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training (covered for Medicare)
G0565 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 (covered for Medicare)

VI. REFERENCES

Centers for Medicare & Medicaid Services (CMS).Classification and Payment for Continuous Glucose Monitors Under Medicare Part B (summary of final provisions) – Section 4 of the following Rule: *Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues, and Level II of the Healthcare Common Procedure Coding System (HCPCS); DME Interim Pricing in the CARES Act; Durable Medical Equipment Fee Schedule Adjustments To Resume the Transitional 50/50 Blended Rates To Provide Relief in Rural Areas and Non-Contiguous Areas*. Effective Date February 28, 2022. Document Citation 86 FR 73860. Document Number 2021-27763.

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Wisconsin Physicians Service Insurance Corporation. Centers for Medicare & Medicaid Services (CMS). Implantable Continuous Glucose Monitors (I-CGM). Local Coverage Determination (LCD) L38686.