THERAPEUTIC CONTINUOUS BLOOD GLUCOSE MONITORS

Guideline Number: MPG363.06  Approval Date: April 10, 2019

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Related Medicare Advantage Policy Guideline

• Home Blood Glucose Monitors (NCD 40.2)

Related Medicare Advantage Coverage Summaries

• Diabetes Management, Equipment and Supplies
• Durable Medical Equipment, Prosthetics, Corrective Appliances/Orthotics and Medical Supplies
• Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid

POLICY SUMMARY

See Purpose

Overview
Continuous blood glucose monitoring (CGM) is described as the use of a small catheter sensor inserted into subcutaneous tissue to measure interstitial blood glucose levels.

On January 12, 2017 the Centers for Medicare & Medicaid Services (CMS) issued CMS Ruling 1682R addressing the benefit category for non-adjunctive CGM systems. This ruling classified CGM systems into therapeutic and non-therapeutic systems. A Therapeutic CGM is defined as a CGM used as a replacement for fingerstick blood glucose testing for diabetes treatment decisions i.e., non-adjunctive use. Non-therapeutic CGM are devices used as an adjunct to BGM testing (i.e., primary therapeutic decisions regarding diabetes treatment must be made with a standard home BGM, not the CGM). Non-Therapeutic CGMs are non-covered by Medicare Advantage as they do not meet Medicare criteria outlined in the CMS Ruling 1682R (See Classification of Therapeutic Continuous Glucose Monitors as DME under Medicare Part B, CMS Ruling CMS-1682-R, dated January 12, 2017, CMS Website).

Therapeutic CGM devices may consist of various components such as; a sensor, a transmitter, and a receiver. Wireless and mobile technology can now be utilized to obtain blood glucose information every few minutes via the CGM device. The glucose sensor generates a small electrical signal in response to the amount of interstitial glucose detected. This electrical signal is converted into a glucose reading that is then sent to the transmitter. The transmitter sends the measurements wirelessly to a dedicated receiver (or type of monitor) and/or compatible mobile device (smart phone, tablet, etc.) for display to the user. The receiver displays the glucose measurements in the form of a graph so that the glucose measurements can be visualized.

For CGM products that are used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions, these therapeutic CGMs are primarily and customarily used to serve a medical purpose because they are used by Medicare beneficiaries with diabetes who must measure their glucose level frequently and check trends in their glucose measurements for the purpose of adjusting their diet and insulin in the treatment of their diabetes. A receiver (or type of monitor) for a therapeutic CGM that has an expected life of at least 3 years and is the component performing the medically necessary function of accurately monitoring the trends of the patients' blood glucose levels so that he or she can make necessary diabetes treatment decisions meets the 3-year MLR (minimum lifetime requirements).

Patient Selection Criteria
An FDA approved therapeutic CGM may be covered when all of the following criteria are met:
• The beneficiary has diabetes mellitus; and,
• The beneficiary has been using a home blood glucose monitor and performing frequent (four or more times a day) BGM testing; and,
• The beneficiary is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
• The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results.
• Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
• Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment.

**Guidelines**

CGM devices and sensors are not considered standard diabetic testing supplies (like test strips, lancets, or glucometers). If using stand-alone standard diabetic testing, supplies are covered at the pharmacy. Coverage for an FDA approved Therapeutic CGM devices and sensors may be available from a Durable Medical Equipment (DME) supplier under the medical benefit in which medical criteria requirements are met.

**DME**

The DME component for a CGM system is the receiver. The receiver must be billed using the following code:

- E1399 - Durable Medical Equipment, Miscellaneous (for dates of service prior to 07/01/2017)
- K0554 - Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system (for dates of service 07/01/2017 and after)

When billing E1399, suppliers must enter the exact CGM receiver product name in the narrative field of the claim.

Smart devices are non-covered by Medicare because they do not meet the definition of DME (i.e., not primarily medical in nature and are useful in the absence of illness). Claims for smart devices must be billed using code A9270 (noncovered item or service).

**The Supply Allowance**

The supply allowance for supplies used with a CGM System encompasses all items necessary for the use of the device and includes, but is not limited to: CGM sensor, CGM transmitter, home blood glucose monitor and related BGM supplies (test strips, lancets, lancing device, and calibration solutions) and all batteries.

The supply allowance must be billed using the following code:

- A9999 – Durable Medical Equipment, Miscellaneous Supply (for dates of service prior to 07/01/2017)
- K0553 - Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service (for dates of service 07/01/2017 and after)

Claims for A9999 must be billed as one (1) unit of service per month. When billing this code, suppliers must enter the exact CGM receiver product used for supplies in the narrative field on the claim.

**Note:** HCPCS codes E1399, A9999 effective 01/12/2017 to 06/30/2017

Coverage of a CGM system supply allowance (K0553) is available for those therapeutic CGM systems where the beneficiary uses a receiver classified as DME to display glucose data. In addition, Medicare coverage is available for a CGM system supply allowance if a non-DME device (watch, smartphone, tablet, laptop computer, etc.) is used in conjunction with the durable CGM receiver (K0554). The following are examples of this provision:

- Medicare coverage of a CGM supply allowance is available where a beneficiary uses a durable CGM receiver to display their glucose data and also transmits that data to a caregiver through a smart phone or other non-DME receiver.
- Medicare coverage of a CGM system supply allowance is available where a beneficiary uses a durable CGM receiver on some days to review their glucose data but may also use a non-DME device on other days.

If a beneficiary never uses a DME receiver for a therapeutic CGM, the supply allowance is not covered by Medicare.

**Miscellaneous Coding Information**

Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers who provide an FDA approved CGM System are reminded of the following Medicare coverage policies:

- The supply allowance (code K0553) is billed as 1 Unit of Service (UOS) per month. Only one (1) UOS of code K0553 may be billed to the DME MACs at a time. Billing more than 1 UOS per month of code K0553 will be denied as not reasonable and necessary.
- Therapeutic CGM devices replace a standard home blood glucose monitor (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233-A4236, A4244-A4247, A4250, A4253, A4255-A4259, see NCD 40.2
Home Blood Glucose Monitors). Claims for standard home glucose monitors and all related supplies, billed in addition to a CGM system and associated supply allowance, will be denied as unbundling.

All non-therapeutic CGM systems must be billed using the following codes that are non-covered by Medicare:

- A9276 - Sensor; Invasive (E.G., Subcutaneous), Disposable, For Use With Interstitial Continuous Glucose Monitoring System, One Unit = 1 Day Supply
- A9277 - Transmitter; External, For Use With Interstitial Continuous Glucose Monitoring System
- A9278 - Receiver (Monitor); External, For Use With Interstitial Continuous Glucose Monitoring System
- Codes A9276 and A9277 are not used to bill for supplies used with code K0554 - Receiver (monitor).

### APPLICABLE CODES

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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<th>HCPCS Code</th>
<th>Description</th>
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<td>A9999</td>
<td>Miscellaneous DME supply or accessory, not otherwise specified (Effective 01/12/2017 to 06/30/2017)</td>
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<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous (Effective 01/12/2017 to 06/30/2017)</td>
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<tr>
<td>K0553</td>
<td>Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit of Service (Effective 07/01/2017)</td>
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<tr>
<td>K0554</td>
<td>Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system (Effective 07/01/2017)</td>
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<table>
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<tr>
<th>ICD-10 Diagnosis Code</th>
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<tr>
<td>Z79.4</td>
<td>Long term (current) use of insulin</td>
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</table>

And any of the following diagnoses:

- E08.00: Diabetes mellitus due to underlying condition with hyperosmolarity without nonketotic hyperglycemic-hyperosmolar coma (NKHHC)
- E08.01: Diabetes mellitus due to underlying condition with hyperosmolarity with coma
- E08.10: Diabetes mellitus due to underlying condition with ketoacidosis without coma
- E08.11: Diabetes mellitus due to underlying condition with ketoacidosis with coma
- E08.21: Diabetes mellitus due to underlying condition with diabetic nephropathy
- E08.22: Diabetes mellitus due to underlying condition with diabetic chronic kidney disease
- E08.29: Diabetes mellitus due to underlying condition with other diabetic kidney complication
- E08.311: Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy with macular edema
- E08.319: Diabetes mellitus due to underlying condition with unspecified diabetic retinopathy without macular edema
- E08.3211: Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, right eye
- E08.3212: Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, left eye
- E08.3213: Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, bilateral
- E08.3219: Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy with macular edema, unspecified eye
- E08.3291: Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, right eye
- E08.3292: Diabetes mellitus due to underlying condition with mild nonproliferative diabetic retinopathy without macular edema, left eye
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<td>Diabetes mellitus due to underlying condition with proliferative diabetic retinopathy with traction retinal detachment involving the macula, right eye</td>
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<td>Other pre-existing diabetes mellitus in childbirth</td>
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<td>O24.83</td>
<td>Other pre-existing diabetes mellitus in the puerperium</td>
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<tr>
<td>O24.911</td>
<td>Unspecified diabetes mellitus in pregnancy, first trimester</td>
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<td>O24.912</td>
<td>Unspecified diabetes mellitus in pregnancy, second trimester</td>
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<tr>
<td>O24.913</td>
<td>Unspecified diabetes mellitus in pregnancy, third trimester</td>
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<td>O24.919</td>
<td>Unspecified diabetes mellitus in pregnancy, unspecified trimester</td>
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<td>O24.93</td>
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**QUESTIONS AND ANSWERS**

1. Q: What is the definition of a “Therapeutic” CGM?
   
   A: "Therapeutic" CGMs are CGM systems approved by the FDA to replace other blood glucose monitoring systems and to make diabetes treatment decisions. The device classification was established by CMS on 01/12/2017.

2. Q: What is the definition of a "Non-therapeutic" CGM?
   
   A: Any CGM approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions.

3. Q: Is any brand of CGM a covered device?
   
   A: No, only the devices that meet the definition of a therapeutic CGM will be considered for coverage.

4. Q: Will Medicare Advantage cover my supplies when I only have a smart device (smart phones, tablets, personal computers, etc.) and I’m not using a CGM receiving device, other than my smart device?
   
   A: No, the DME Benefit excludes coverage for the smart device (smart phones, tablets, personal computers, etc.) when used as the only receiving device.
   
   In addition, non-medical items, even when the items may be used to serve a medical purpose are not covered when the smart device is the only device used. A CGM receiver must be used in conjunction with the smart device for supplies to be covered.

5. Q: How does UHC determine if a member is insulin dependent?
   
   A: UHC requires the use of ICD-10 code Z79.4 in addition to the applicable diabetes diagnosis coding.

**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:
- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the References section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline...
Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

REFERENCES

CMS National Coverage Determinations (NCDs)
NCD 40.2 Home Blood Glucose Monitors

CMS Local Coverage Determinations (LCDs)

<table>
<thead>
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<th>LCD</th>
<th>DME</th>
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CMS Articles

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<td>A52464 (Glucose Monitor - Policy Article)</td>
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CMS Benefit Policy Manual
Chapter 15; § 110 Durable Medical Equipment - General

CMS Claims Processing Manual
Chapter 20; § 10.2 Coverage Table for DME Claims, § 50 Payment for Replacement of Equipment, § 100 General Documentation Requirements, § 110 General Billing Requirements for DME, § 140 Billing for Supplies
Chapter 23; § 60 Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule

MLN Matters
Article MM10013, Two New "K" Codes for Therapeutic Continuous Glucose Monitors

UnitedHealthcare Commercial Policies
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes
Durable Medical Equipment, Orthotics, Ostomy Supplies, Medical Supplies and Repairs/Replacements

Others
Classification of Therapeutic Continuous Glucose Monitors as DME under Medicare Part B, CMS Ruling CMS-1682-R, dated January 12, 2017, CMS Website

GUIDELINE HISTORY/REVISION INFORMATION

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

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<tr>
<td>04/10/2019</td>
<td>Annual review</td>
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<tr>
<td></td>
<td>Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
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<tr>
<td></td>
<td>Reformatted list of applicable ICD-10 diagnosis codes</td>
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TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services...
are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

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*For more information on a specific member’s benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.