THERAPEUTIC CONTINUOUS BLOOD GLUCOSE MONITORS

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Table of Contents

<table>
<thead>
<tr>
<th>TERMS AND CONDITIONS</th>
<th>Purpose</th>
<th>Policy Summary</th>
<th>Applicable Codes</th>
<th>Questions and Answers</th>
<th>References</th>
<th>Guideline History/Revision Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Page</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>

Related Medicare Advantage Policy Guidelines

- Home Blood Glucose Monitors (NCD 40.2)
- 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

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.

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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:

Therapeutic Continuous Blood Glucose Monitors
UnitedHealthcare Medicare Advantage Policy Guideline
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Page 1 of 5
Approved 04/12/2017
• 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.

POLICY SUMMARY

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 December 20, 2016 the Food & Drug Administration (FDA) granted premarket approval to Dexcom, Inc. for an expanded indication for their Dexcom G5® Mobile CGM System. The Dexcom G5 Mobile CGM System is now indicated to replace fingerstick blood glucose monitor (BGM) testing for diabetes treatment decisions, referred to by the FDA as "non-adjunctive" use. The Dexcom G5 Mobile CGM System is currently the only FDA-approved device with a "non-adjunctive" indication.

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. Therapeutic CGM are defined as 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 Ruling below in References).

Therapeutic CGM devices consist of three (3) elements; 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
A 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.

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 Therapeutic CGM devices and sensors may be available from a Durable Medical Equipment (DME) supplier under the medical benefit for Dexcom G5 with medical criteria requirements met.
The DME component for the Dexcom G5 Mobile CGM system is the receiver. The receiver must be billed using the following code:

- E1399 - Durable Medical Equipment, Miscellaneous

When billing this code, suppliers must enter "Dexcom G5 Receiver" in the narrative field of the claim.

The supply allowance for supplies used with the Dexcom G5 Mobile 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

Claims for A9999 must be billed as one (1) unit of service per month. When billing this code, suppliers must enter "Supplies used with Dexcom G5 Receiver" in the narrative field on the claim.

The Medicare DME Benefit excludes coverage for non-medical items, even when the items may be used to serve a medical purpose. As a result, smart devices (smart phones, tablets, personal computers, etc.) are non-covered by Medicare under this exclusion. Likewise, medical supplies used with non-covered equipment are not eligible for Medicare reimbursement.

In addition to the DME receiver included in the Dexcom G5 Mobile CGM System, an alternative option for displaying the received data is with a smart device using the Dexcom G5 app and a beneficiary-owned smart device such as a smart phone or tablet. Medicare does not cover a beneficiary-owned smart device. Claims for beneficiary-owned smart devices submitted to Medicare must be coded:

- A9270 - Noncovered Item or Service

**Miscellaneous Coding Information**

Durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers who provide the Dexcom G5 Mobile CGM System are reminded of the following Medicare coverage policies:

- Coverage of the CGM system supply allowance is limited to those therapeutic CGM systems where the beneficiary ONLY uses a receiver classified as DME to display glucose data. If a beneficiary uses a non-DME device (smart phone, tablet, etc.) as the display device, either separately or in combination with a receiver classified as DME, the supply allowance is non-covered by Medicare.

- 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 with the existing CGM-related HCPCS codes. At this time, all CGM systems except the Dexcom G5 Mobile CGM System are classified by CMS as non-therapeutic CGM systems. 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

**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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<tr>
<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 (New code, effective 07/01/2017)</td>
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HCPCS Code | Description
---|---
K0554 | Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system (New code, effective 07/01/2017)

ICD-10 Diagnosis Codes

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.

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: Will Medicare Advantage cover my supplies when I use my smart device as the receiving device?
   A: No, the DME Benefit excludes coverage for non-medical items, even when the items may be used to serve a medical purpose. As a result, smart devices (smart phones, tablets, personal computers, etc.) are non-covered by Medicare under this exclusion. Likewise, medical supplies used with non-covered equipment are not eligible for Medicare reimbursement.

4. Q: Is any brand of CGM a covered device?
   A: No, the Dexcom G5 Mobile CGM System is the only device which meets the therapeutic CGM device classification established by CMS on 01/12/2017.

REFERENCES

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

CMS Local Coverage Determinations (LCDs)

<table>
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<th>LCD</th>
<th>DME</th>
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| L33822 (Glucose Monitors) | **CGS**: AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
**Nordinian**: AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA |

CMS Articles

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<th>DME</th>
</tr>
</thead>
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| A52464 (Glucose Monitor - Policy Article - Effective October 2015) | **CGS**: AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
**Nordinian**: AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA |

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

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.

<table>
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<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
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<tbody>
<tr>
<td>08/02/2017</td>
<td>• Policy updated per CMS</td>
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</tbody>
</table>
| 08/01/2017 | • Updated policy template:  
  - Removed and replaced Instructions for Use; added Terms and Conditions and Purpose language  
  - Updated Guideline History/Revision Information; added disclaimer language to indicate 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 |
| 05/24/2017 | • Policy updated per CMS                                                                                                                          |
| 04/12/2017 | • New policy presented for MAPG Committee presentation and approval                                                                              |