NOTE: This policy has been revised. The revised policy will be effective November 1, 2019. To view the revised policy, click here.

Medicare Advantage Policy Manual **Policy ID:** M-DME86

Continuous Glucose Monitoring (CGM) Systems

Published: 02/01/2019

Next Review: 01/2020

Last Review: 01/2019 ***Medicare Link(s) Revised:*** *04/01/2019*

IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Traditional blood glucose monitors measure *capillary blood* to alert users when glucose values are approaching potentially dangerously high (hyperglycemic) and/or low (hypoglycemic) levels. Blood glucose monitors are reported with HCPCS code E0607, E2100, or E2101, depending on what special features may or may not be included.

Continuous glucose monitoring (CGM) systems measure glucose in *interstitial fluid*, rather than capillary blood. Because they do not measure blood glucose, different HCPCS and CPT coding are used for these systems and supplies (HCPCS codes A9276-A9278 and K0553-K0554).

CGM devices consist of three (3) components: a glucose sensor, a transmitter, and a receiver (or type of monitor and/or compatible mobile device). The glucose sensor is inserted under the skin to measure glucose levels in interstitial fluid. This is connected to the transmitter, which sends the information to the receiver (monitor), where it is displayed for the user, providing

interstitial glucose readings every few minutes, allowing the user to visualize glucose measurement trends.[1]

MEDICARE ADVANTAGE POLICY CRITERIA

Procedure(s):	Code(s)	CMS Coverage Manuals, National Coverage Determinations (NCD), Noridian Local Coverage Determinations (LCD) and Articles (LCA)
Note: In order for a CGM system to be eligible for coverage, primary consideration is given to the CGM system model provided – that is, is the device deemed a "therapeutic" CGM or a "non-therapeutic" CGM? • **"Therapeutic" CGMs**: "Therapeutic" CGMs are CGM systems approved by the U.S. Food and Drug Administration (FDA) to replace other blood glucose monitoring testing and to make diabetes treatment decisions..[8] • **"Non-Therapeutic" CGMs**: "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)."[8] Any CGM system that does not have the above FDA designation would be considered a "non-therapeutic" CGM. *See the "Regulatory Status" section below for a list of devices and their "therapeutic" or "non-therapeutic" status. While this list is subject to change as devices are approved for Medicare coverage throughout the year, it is important to confirm a specific CGM device has met Medicare requirements and is eligible for Medicare coverage.*		
"Therapeutic" CGMs		
Initial Dispense for Receiver (monitor) and/or Supplies	K0554 for receiver (monitor) K0553 (for all supplies and accessories (1 unit of service = 1 month's supply) *Important Notes:* ➢ *Only systems eligible to be reported with K0554 and K0553 meet Medicare's requirements for CGM coverage.* ➢ *According to LCA A52464, "for…dates of service on or*	Glucose Monitors (L33822) *(See the "CONTINUOUS GLUCOSE MONITORS (CGM)" section, specifically criteria 1-5. If needed, the "POLICY SPECIFIC DOCUMENTATION REQUIREMENTS" section of LCA A52464 may aid in determining if sufficient information has been submitted to document medical necessity.)* ***For Requests for Supplies Only:*** *According to the LCD L33822, "Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-6) are met…" Therefore, if a request is received for supplies only, (1) they must be used with a Medicare-eligible therapeutic CGM, and (2) Medicare criteria for therapeutic CGMs from the LCD must be met.*

Replacement Supplies/Equipment for Ongoing Use	*after 07/01/2017, the only products that may be billed using code K0554 are those that are specified in the Product Classification List on PDAC contractor web site."* ➢ *Therefore, while the "Regulatory Status" table below attempts to be as current as possible, see the PDAC website Classification list to ensure the most current list of CGM systems eligible to be reported with K0554 is viewed.* ➢ *If a CGM system is not listed as eligible by the PDAC to be reported with HCPCS code K0554, then it would **not** be eligible for Medicare coverage.*	LCD for Glucose Monitors (L33822) and LCA for Glucose Monitor - Policy Article (A52464) *(See the "CONTINUOUS GLUCOSE MONITORS (CGM)" section of the LCD, specifically criteria 6, and the last paragraph of the "POLICY SPECIFIC DOCUMENTATION REQUIREMENTS" section of the LCA to determine if sufficient information has been submitted to support the continued use of the CGM and supplies. Both references should be reviewed to ensure accuracy.)* ***Important Note Regarding Requests for New Receiver:*** *Items classified as DME after January 1, 2012 must have an expected life of at least three (3) years. This 3-year minimum lifetime requirement (MLR) also applies to multicomponent systems consisting of both durable and nondurable components. Under CMS rules, the component of a multicomponent device which performs the medically necessary function of the device must meet the 3-year MLR.[11] The CMS Ruling CMS-1682-R states Medicare expects the* receiver *component to have an expected life of at least 3 years.[1] Therefore, requests for a new receiver before the 3-year MLR may be considered **not** medically necessary.*
"Non-therapeutic" CGMs and Miscellaneous Requests		
"Non-therapeutic" CGMs	HCPCS A9276, A9277, A9278 Any CGM system not approved as a therapeutic CGM must use these HCPCS codes.."	Noridian LCA for Glucose Monitor - Policy Article (A52464) See also the following Noridian web page article: ✓ Retired - Coding and Coverage - Therapeutic Continuous Glucose Monitors (CGM), *under the "Miscellaneous" section.*

Smart Device Usage with CGM *(i.e., smart phones, tablets, personal computers, etc.)*	HCPCS K0553 – The CGM supply allowance includes all items necessary for the use of the device. HCPCS A9270 – Used for the smart device itself.	Noridian LCA for Glucose Monitor – Policy Article (A52464) • Prior to June 7, 2018, "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." • As of June 7, 2018, "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 smart device itself (e.g., phone, tablet, etc.) is **not** eligible for Medicare coverage.
Implantable Continuous Glucose Monitoring	Category III codes 0446T-0448T	Non-Covered Services (L35008)
**Scroll to the "Public Version(s)" section at the bottom of the LCD for links to prior versions if necessary.		

POLICY GUIDELINES

REQUIRED DOCUMENTATION

The information below **must** be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Medical records and chart notes must document the member has been diagnosed with diabetes and that the member has received has sufficient training using the particular device;
- A prescription by the referring physician must be on file for the CGM;
- The specific CGM system to be supplied to the member.
- The "POLICY SPECIFIC DOCUMENTATION REQUIREMENTS" section of LCA A52464 may aid in determining if sufficient information has been submitted to document medical necessity.

REGULATORY STATUS

DEVICE	MANUFACTURER	FDA APPROVAL
"THERAPEUTIC" CGMs *(At the time of the publication of this policy, according to Noridian, the Pricing, Data Analysis and Coding contractor (PDAC), these CGM devices are the only CGMs eligible to be reported with HCPCS code K0554. To confirm the most current list is reviewed, the "Product Classification List" can be searched on the .)*		
Dexcom G5 Mobile Continuous Glucose Monitoring System	DexCom	December 2016 (PDAC eligibility begins 7/1/2017)
FreeStyle® Libre 10-Day System *(Model # 71525-01)*	Abbott	September 2017 (PDAC eligibility begins 12/27/2017)
Dexcom G5 Mobile CGM Touchscreen Receiver	DexCom	March 2017 (PDAC eligibility begins 1/2/2018)
Dexcom G6 Mobile CGM Touchscreen Receiver	DexCom	March 2018 (PDAC eligibility begins 6/22/2018)
FreeStyle® Libre Flash Glucose Monitoring 14-Day System *(Model # 71938-01)*	Abbott	July 2018 (PDAC eligibility begins 9/21/2018)
"NON-THERAPEUTIC" CGMs (non-covered by Medicare as they do not meet Medicare criteria outlined in the January 2017 CMS Ruling)		

Continuous Glucose Monitoring System (CGMS®)	MiniMed	1999
GlucoWatch G2® Biographer *(not available since July 31, 2008)*	Cygnus, Inc.	March 2001 – for adults 18 years and older August 2002 - expanded to include patients aged 7 to 17 years old
Guardian®-RT (Real-Time) CGMS	Medtronic, MiniMed	July 2005
DexCom® STS CGMS system	DexCom	March 2006
Paradigm® REAL-Time System *This system integrates a CGM with a Paradigm insulin pump. The second generation integrated system is called the MiniMed Paradigm Revel System.*	Medtronic, MiniMed	2006
FreeStyle Navigator® CGM System	Abbott	March 2008
DexCom G4 Platinum CGM	DexCom	October 2012 – for adults 18 years and older February 2014 - expanded to include patients aged 2 to 17 years old
iPro2 Continuous Glucose Monitoring System with Enlite Sensor	Medtronic, MiniMed	June 2016

CROSS REFERENCES

None

REFERENCES

1. CMS Ruling No: CMS-1682-R. [cited 01/04/2018] Available from: https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf
2. Noridian website for *Coding and Coverage - Therapeutic Continuous Glucose Monitors (CGM)*. [cited 01/04/2018] Available from: https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/coding-and-coverage-therapeutic-continuous-glucose-monitors
3. NCD for Home Blood Glucose Monitors (40.2)
4. NCD for Closed-Loop Blood Glucose Control Device (CBGCD) (40.3)

5. U.S. Food and Drug Administration Approval Letter for the *Dexcom G5 Mobile Continuous Glucose Monitoring System.* [cited 01/16/2017] Available from: http://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041a.pdf
6. U.S. FDA website for Medical Devices. Available from: http://www.fda.gov/MedicalDevices/default.htm
7. 2017 Fee Schedule Amounts for CMS Ruling 1682-R. [cited 01/04/2018] Available from: https://www.cms.gov/medicare/medicare-fee-for-service-payment/dmeposfeesched/index.html
8. Noridian web page article Coding and Coverage - Therapeutic Continuous Glucose Monitors (CGM) *(see the "Patient Selection Criteria" section of this article)* [cited 01/04/2018] Available from: https://med.noridianmedicare.com/web/jddme/policies/dmd-articles/coding-and-coverage-therapeutic-continuous-glucose-monitors
9. MLN Article, *Two New "K" Codes for Therapeutic Continuous Glucose Monitors* [cited 01/04/2018] Available from: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM10013.pdf
10. U.S. FDA Approval Letter for the *Freestyle Libre Flash Glucose Monitoring System*. [cited 01/04/2018] Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160030A.pdf
11. Federal Register Volume 76, Number 218 (Thursday, November 10, 2011) [cited 04/06/2018] Available from: https://www.gpo.gov/fdsys/pkg/FR-2011-11-10/html/2011-28606.htm
12. Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.1 - Definition of Durable Medical Equipment, B and B.2

CODING

NOTES:

- Blood glucose monitors (E0607, E2100, or E2101) and diagnostic monitoring by a physician (95250, 95251) are considered ***medically necessary***, and are not subject to routine clinical review under this medical policy.
- HCPCS codes S1030-S1031 are Medicare Status "I" codes, and therefore, are not valid for Medicare or Medicare Advantage use.
- HCPCS codes A9276-A9278 are used for CGM devices that don't meet Medicare's coverage requirements as a therapeutic CGM, and are non-covered. Alternate coding for approved CGM devices is recommended by CMS (see next bullet).
- According to the Medicare "2017 fee schedule amounts," prior to July 1, 2017, the expected HCPCS codes for use to report Medicare-approved CGM components (receiver, monitor, supplies, and/or accessories) are the unlisted codes E1399 or A9999.[7] This coding is confirmed by the local DME contractor, Noridian.[2]
- As of July 1, 2017, specific codes were developed for Medicare-approved therapeutic CGM units (HCPCS codes K0553 and K0554).

Codes	Number	Description
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

Codes	Number	Description
	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; equipment provided by the physician or other qualified health care professional, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording
	95251	; interpretation, report, and analysis
HCPCS	A9276	Sensor; invasive (eg, subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1 day supply *(Non-covered by Medicare)*
	A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system *(Non-covered by Medicare)*
	A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system *(Non-covered by Medicare)*
	A9999	Miscellaneous DME supply or accessory, not otherwise specified **Note:** Between January 2017 and July 2017, this HCPCS code was used to report for therapeutic CMG supplies (including, but not limited to: CGM sensor and transmitter, home blood glucose monitor and related BGM supplies [test strips, lancets, lancing device, and calibration solutions] and all batteries).
	E0607	Home blood glucose monitor
	E1399	Durable medical equipment, miscellaneous **Note:** Between January 2017 and July 2017, this HCPCS code was used to report for therapeutic CMG receivers.
	E2100	Blood glucose monitor with integrated voice synthesizer
	E2101	Blood glucose monitor with integrated lancing/blood sample
	K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 Unit Of Service
	K0554	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system
	S1030	Continuous noninvasive glucose monitoring device, purchase (for physician interpretation of data, use CPT code) *(Not valid for Medicare purposes)*
	S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor (for physician interpretation of data use CPT code) *(Not valid for Medicare purposes)*

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*