The van Halem Group

A Division of VGM Group, Inc.

CGM Coding & Billing Requirements

Continuous Glucose Monitors (CGM)

Kelly Grahovac, General Manager
Carrie Nienberg, Clinical Director

Agenda

- Coverage Criteria
- Documentation Requirements
- Coding and Billing Reminders
- Frequently Asked Questions
- Resources
- Questions

Therapeutic Continuous Glucose Monitors

- Therapeutic CGMs are defined as:
  - Glucose monitors used as a replacement for finger-stick blood glucose testing treatment decisions
- Currently only certain FDA-approved devices with a non-adjunctive indication are applicable for billing
  - Abbott Freestyle Libre – Class III Device
  - Dexcom G5 – Class III Device
  - Dexcom G6 – This receiver is not a Class III Device
  - Respcare Hybrid
  - Mirage Liberty
- Refer to the Pricing, Data, Analysis, Coding Contractor (PDAC) for information to verify any devices that may qualify under this ruling

Coverage Criteria and Documentation Requirements

Coverage Criteria

1. Diabetes mellitus diagnosis; and,
2. Frequent home testing (four or more times per day) with home blood glucose monitor (BGM); and,
3. Multiple (three or more) daily injections of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
4. Insulin regimen requires frequent adjustment based on BGM or CGM testing results; and,
5. In-person encounter with physician within six months prior to ordering CGM to evaluate diabetes control and to determine that criteria 1-4 above are met; and,
6. In-person encounter with physician every six months to assess adherence to CGM regimen and diabetes treatment plan.

Documentation in the Beneficiary's Medical Record

- For the initial provision of the CGM, the beneficiary's medical record must show how the CGM coverage criteria have been met (criteria 1-4)
- For the in-person treating practitioner visit that is required as part of the ongoing provision of a therapeutic CGM, there must be sufficient information in the beneficiary's medical record to determine the beneficiary continues to adhere to their diabetes treatment regimen and use of the CGM device on a daily basis
- Supplier-produced records are deemed not part of the medical record for Medicare payment purposes
- Supplier prepared statements and physician/practitioner attestations by themselves do not provide sufficient documentation of medical necessity, even if signed by the ordering practitioner

New Order Requirements

A new order is required when:

- For all claims for purchases or initial rental
- When an item is replaced
  - Replacement of the CGM within the reasonable useful lifetime (RUL)
  - Replacement of a CGM after the RUL
- When there is a change in the supplier
  - If the new supplier is unable to obtain a copy of a valid order/prescription for the DMEPOS item from the transferring supplier
- When state law requires a prescription renewal

Delivery – Direct to Beneficiary

Proof of Delivery must include:

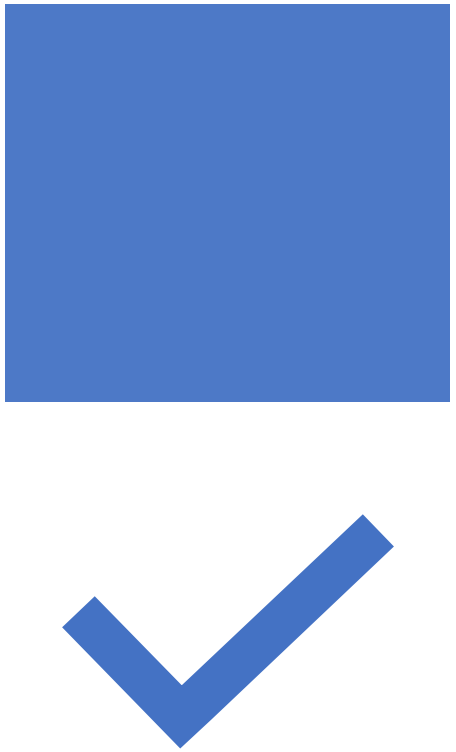
- Beneficiary's name
- Delivery address
- The quantity delivered
- A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number
- Date delivered
- Beneficiary (or designee) signature

Delivery – Shipping Service

The Proof of Delivery (POD) must include:

- Beneficiary's name
- Delivery Address
- Delivery service's package ID number, supplier invoice number or alternative method that links supplier's delivery documents with delivery service's records
- A description of the item(s) being delivered. The description can be either a narrative description, a HCPCS code, the long description of a HCPCS code, or a brand name/model number
- Quantity delivered
- Date Delivered
- Evidence of delivery

Coding and Billing Reminders



Supply Allowance

Supplies covered only when the CGM device is covered

- Supply allowance
  - K0553 – 1 unit of service (UOS) per thirty (30) days
  - Billing more than 1 UOS per 30 days will be denied as not reasonable and necessary
    - E.g. 02/01/2020 K0553KFKXCG 1UOS, the next billing date needs to be 30 days after 02/01/2020 (this is a leap year)
    - E.g. Next billing date 03/02/2020 K0553KFKXCG 1 UOS
  - Supply allowance includes all items necessary for the use of the device
    - Sensor, transmitter, home BGM, related BGM supplies (test strips, lancets, lancing device, calibration solutions), batteries, etc.
  - Claims billed for a blood glucose monitor and related accessories and supplies in addition to a CGM device and supply allowance will be denied as unbundling

Supply Allowance

Medicare coverage for the supply allowance is available if another device (non-DME) is used in addition to, or in conjunction with, an approved receiver

- Non-DME Device
  - Tablets, smartphones, watches, laptops, etc.
- Medicare coverage of a CGM supply allowance is available when the durable CGM receiver displays glucose data and also transmits data to a caregiver through a smartphone or other non-DME receiver
- Medicare coverage of a CGM supply allowance is available when the durable CGM receiver is used on some days to review glucose data but may also use a non-DME device on other days

Coverage Criteria: Supply Allowance Non-Covered

What is not covered?

- Other devices
  - CGM devices that do not meet the definition of a therapeutic CGM and have not been approved by the PDAC will be denied as non-covered (no benefit)
  - Tablets, smartphones, watches, laptops, etc. instead of receiver
    - If a beneficiary only uses a non-DME device (watch, smartphone, tablet, laptop computer, etc.) as the display device, the supplies shall be denied as noncovered by Medicare

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

Modifiers – Pricing Modifiers

- Continuous Glucose Monitor (CGM) – K0554
  - NU, UE, RR
- Item Designated by FDA as a Class III Device – K0554, K0553
- KF – required when billing a Class III Device
  - Dexcom Mobile G5
  - Abbott Freestyle Libre
- The Dexcom Mobile G6 is not a Class III Device
  - Submit associated claims without the KF modifier
  - Suppliers should contact the PDAC for guidance on the correct coding

Billing Reminders

- ICD-10 code describing condition necessitating items must be included on the claim form
- The beneficiary's medical records on file with the treating practitioner must detail that coverage guidelines are met
- Use the appropriate modifiers:

Modifier	Usage
KX	Insulin treated monitors and supplies
CG	Append if coverage criteria are met
KF	Append for claims associated with Class III devices (K0553 and K0554 claims)

Claim Submission When Coverage Criteria is Met

- Line 1: K0554NUKFKXCG – 1 UOS
- Line 2: K0553KFKXCG – 1 UOS

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.

A. E119 B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

	24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER				E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
1	02	01	20	02	01	20	12		K0554	NU	KF	KX	CG	A	231 77	1		NPI	
2	02	01	20	02	01	20	12		K0553	KF	KX	CG		A	259 00	1		NPI	

Frequently Asked Questions (FAQs)

FAQs

- Does the supply allowance, K0553, require a date span?
  - No. One unit of service is for a 30-day supply.

- Can suppliers deliver a 3-month supply allowance at one time?
  - Yes, you can provide a 90-day supply, however, Medicare only allows one (1) UOS of the supply allowance to be billed at a time. Suppliers must deliver a sufficient quantity of all necessary supplies to last for an entire month. If there are insufficient supplies to be able to last for a full month, additional supplies must be provided before the supply allowance is billed.

FAQs

- Why are claims for strips and lancets denying after the beneficiary changes to a CGM?
  - Per the CMS Ruling 1682R, a standard blood glucose monitor and test strips are viewed as equivalent, or “same or similar” to a CGM. Consequently, once CGM billing commences, edits are established to deny future billing of glucose monitors and the associated testing supplies. The DME supplier should no longer bill individual testing supplies (i.e., A4253, A4259) after the beneficiary receives the CGM. The supplier should bill using HCPCS code, K0553, which includes all supplies required for the CGM. The supplier should bill one unit of service per 30 days for the K0553.

FAQs

- What if a beneficiary receives a continuous glucose monitor then decides they don't like it or the co-pay is too high? Can they go back to a regular blood glucose monitor?
  - If a beneficiary wishes to return to BGM testing, they may do so, however, Medicare will not reimburse a new BGM monitor unless the CGM is past the 5-year reasonable useful lifetime (RUL). Beneficiaries can use a BGM monitor that they own or purchase a new monitor as an out-of-pocket expense. Changing back to standard BGM testing and supplies is allowed without additional documentation of medical necessity, other than documentation of a diabetes diagnosis. When a beneficiary switches from CGM supplies back to BGM supplies, a supplier must submit a claim for the BGM supplies. If the BGM supplies deny, the supplier will need to submit a redetermination.

Tips

- Suppliers should check for same and similar information for both types of glucose monitors – the E0607 and the K0554 on the DME MAC portals/IVR
  - Search by HCPCS
  - Searcy by using a partial HCPCS code, “K” for instance, within the Claims History section to receive a list of all HCPCS codes billed that begin with “K.”

Resources

- Local Coverage Determination (LCD): Glucose Monitors (L33822)
  - https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822&ContrId=389&ver=26&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&DocType=2&bc=AAACAACAAAAA&
- Local Coverage Article: Glucose Monitor - Policy Article (A52464)
  - https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52464&ver=26&LCDId=33822&ContrId=389&ContrVer=1&CntrctrSelected=389*1&Cntrctr=389&DocType=2&bc=AAACAACAIAAA&

Resources

- CGM Documentation Checklist
  - https://cgsmedicare.com/pdf/dme_checklists/cgm_supplies.pdf
- Dear Clinician Letter - CGM
  - https://med.noridianmedicare.com/documents/2230703/17635061/Continuous%20Glucose%20Monitors%20DCL

vHG Services

- Compliance programs and packages
- Proactive Claims Audit
- Clinical prescreen reviews
- Education and training
- Audit Response and appeals

Stay Connected

- Facebook - The van Halem Group
- Twitter - @vanHalemGroup
- Blog - www.vanhalemgroup.com/blog
- LinkedIn – Kelly Grahovac, Carrie Nienberg

Questions???

The van Halem Group
A Division of VGM Group, Inc.

The van Halem Group
101 Marietta St NW
Suite 2460
Atlanta, GA 30303
(404) 343-1815

www.vanHalemGroup.com

Kelly Grahovac: Kelly@vanhalemgroup.com

Carrie Nienberg: CNienberg@vanhalemgroup.com