DOCUMENTATION CHECKLIST

JURISDICTIONS B & C

CONTINUOUS GLUCOSE MONITORS AND SUPPLIES

REQUIRED DOCUMENTATION

All Claims for Continuous Glucose Monitors and Supplies

Dates of Service on and after 04/16/2023

☐ **Standard Written Order (SWO)**

The SWO contains all of the following elements:

- ○ Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- ○ Order Date
- ○ General description of the item
  - ☐ The description can be either a general description (e.g., continuous glucose monitor), a HCPCS code, a HCPCS code narrative or a brand name/model number
  - ☐ For equipment – In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately)
  - ☐ For supplies – In addition to the description of the base item, the DMEPOS order/ prescription may include all concurrently order supplies that are separately billed (A4239 or A4238 is an all-inclusive supply allowance)
- ○ Quantity to be dispensed, if applicable
- ○ Treating Practitioner Name or NPI
- ○ Treating Practitioner's signature
- ○ The practitioner's signature on the standard written order meets **CMS Signature Requirements:** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf

NOTE:

- Refill requirements do not apply to CGM supply allowances (A4239 or A4238)
- The supplier must monitor usage and verify the beneficiary has sufficient supplies to last 30 days
- If there are insufficient supplies to be able to last 30 days, additional supplies must be provided before the supply allowance is billed
- Up to a maximum of a 3 month supply (3 UOS = 90 days) may be billed at a time
- Do not bill with a span date

☐ **Delivery Documentation**

Direct Delivery	Shipped/Mail Order Tracking Slip	Shipped/Mail Order Return Post-Paid Delivery Invoice
○ Beneficiary's name ○ Delivery address ○ 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. ○ Delivery date ○ Signature of person accepting delivery ○ Relationship to beneficiary	○ Shipping invoice ☐ Beneficiary's name ☐ Delivery address ☐ 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. ☐ Quantity shipped ○ Tracking slip ☐ References each individual package ☐ Delivery address ☐ Date shipped ☐ Date delivered ☐ Package I.D. #number ○ A common reference number (package ID #, PO #, etc.) links the invoice and tracking slip (may be handwritten on one or both forms by the supplier)	○ Shipping invoice ☐ Beneficiary's name ☐ Delivery address ☐ 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. ☐ Quantity shipped ☐ Date shipped ☐ Signature of person accepting delivery ☐ Relationship to beneficiary ☐ Delivery date

NOTE: If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

All Claims for Continuous Glucose Monitors (CGM) and Supplies

- ☐ **Medical Records**
  - ○ 1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
  - ○ 2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
  - ○ 3. The CGM is prescribed in accordance with its FDA indications for use; and,
  - ○ 4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
    - ☐ The beneficiary is insulin-treated; or,
    - ☐ The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following:
      - ○ Recurrent (More than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
      - ○ A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
  - ○ 5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met.
  - ○ For Continued coverage
    - ☐ Every six (6) months **following** the initial order of the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan
- ☐ For an adjunctive CGM the beneficiary must own or be renting an insulin infusion pump and meet the Medicare coverage criteria for an insulin infusion pump.
- ☐ The practitioner's signature on the standard written order meets **CMS Signature Requirements:** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6698.pdf

REMINDERS

- The diagnosis code describing the condition that necessitates glucose testing must be included on each claim for the monitor and supply allowance.
- For claims with dates of service on or after July 1, 2017, through December 31, 2022, a non-adjunctive CGM must be billed with code K0554 and code K0553 for the supply allowance. For claims with dates of service on or after January 1, 2023, a non-adjunctive CGM must be billed with code E2103 and code A4239 for the supply allowance.
- For claims with dates of service on or after April 1, 2022, suppliers must bill as a rental (RR) both E0784 and E2102 to describe the rental of an insulin pump with integrated adjunctive CGM receiver functionality.
- The CGM receiver is an inexpensive routinely purchased (IRP) item, the NU, UE, or RR modifier must be added to the monitor E2102 and E2103 on every claim submitted.
- Suppliers must bill as a rental (RR) both the E0784 and E2103 to describe the rental of an external insulin infusion pump with non-adjunctive CGM receiver functionality.
- If the CGM receiver is a Class III device, the KF modifier must be added to the monitor and the supply allowance on every claim submitted.
- If the beneficiary is being treated with insulin administrations, the KX modifier must be added to the monitor and supply allowance on every claim submitted. The KX modifier

must not be used for a beneficiary who is not treated with insulin administrations.

- If the beneficiary is not being treated with insulin administrations, the KS modifier must be added to the code for the monitor and the supply allowance on every claim submitted.
- All CGM devices billed as E2102 and E2103 must have received coding verification review by the Pricing, Data Analysis and Coding (PDAC) contractor and be listed on the Product Classification List (PCL).
- Never bill both the KX and the KS modifier on the same claim line.
- The CG modifier must be added to claim lines for both E2103 and A4239 **only** if all of the coverage criteria for a CGM have been met.
- The CG modifier must be added to the claim line for an adjunctive CGM (E2102) incorporated into an insulin infusion pump and supply allowance (code A4238) only if all of the CGM coverage criteria (1-5) in the Glucose Monitors LCD and the coverage criteria for an insulin infusion pump as outlined in the External Infusion Pumps LCD are met.
- Submit claims with the correct unit of service for the supply allowance (A4239 or A4238).
- Coverage of a CGM system supply allowance (code A4238 or A4239) is available for CGM systems when the beneficiary uses a stand-alone receiver or insulin infusion pump 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 (code E2102 or E2103). The following are examples of this provision:
  - Medicare coverage of a CGM supply allowance is available when 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 when a beneficiary uses a durable CGM receiver on some days to review their glucose data but uses a non-DME device on other days.
- If a beneficiary never uses a DME receiver or insulin infusion pump to display CGM glucose data, the supply allowance is not covered by Medicare.

ONLINE RESOURCES

- **Local Coverage Determinations (LCDs) and Policy Articles (PAs)**
  - **JB:** https://www.cgsmedicare.com/jb/coverage/lcdinfo.html
  - **JC:** https://www.cgsmedicare.com/jc/coverage/lcdinfo.html
- **DME MAC Supplier Manual**
  - **JB:** https://www.cgsmedicare.com/jb/pubs/supman/index.html
  - **JC:** https://www.cgsmedicare.com/jc/pubs/supman/index.html
- **Continuous Glucose Monitor (CGM) Supply Allowance Date of Service (DOS) Calculator**
  - **JB:** https://www.cgsmedicare.com/medicare_dynamic/jb/k0553/index.aspx
  - **JC:** https://www.cgsmedicare.com/medicare_dynamic/jc/k0553/index.aspx

NOTE: It is expected that the beneficiary's medical records will reflect the need for the care provided. These records are not routinely submitted to the DME MAC but must be available upon request. Therefore, while it is not a requirement, it is a recommendation that suppliers obtain and review the appropriate medical records and maintain a copy in the beneficiary's file.

DISCLAIMER

This document was prepared as an educational tool and is not intended to grant rights or impose obligations. This checklist may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either written law or regulations. Suppliers are encouraged to consult the *DME MAC Supplier Manual* and the Local Coverage Determination/Policy Article for full and accurate details concerning policies and regulations.