| MedStar Family Choice | | |
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| **ADMINISTRATIVE POLICY AND PROCEDURE** | | |
| **Policy #:** | **221** | |
| **Subject:** | **Continuous Glucose Monitoring Devices** | |
| **Section:** | **Pharmacy** | |
| **Initial Effective Date:** | **7/1/2021** | |
| **Revision Effective Date(s):** | **11/24/2021, 07/22, 2/2023, 5/17/2023** | |
| **Historical Revision Date(s):** | | |
| **Review Effective Date(s):** | | |
| **Historical Review Date(s):** | | |
| **Responsible Parties:** | **Health Plan Pharmacist** | |
| **Responsible Department(s):** | **P&T Committee, Clinical Operations** | |
| **Regulatory References:** | **2023 ADA Standards of Medical Care in Diabetes,<br>AACE Consensus Statement on comprehensive DM2 management – 2023 update** | |
| **Approved:** | **Carol Attia, MBA, BSN, RN<br>Vice President, Clinical Care and Quality Clinical Operations** | **Karyn Wills, MD<br>Chief Medical Officer** |

**Purpose:** **To describe the current continuous glucose monitoring (CGM) device systems available for MedStar Family Choice, Maryland members, CGM procurement processes, and to define the conditions under which MedStar Family Choice (MFC) utilization staff, pharmacist or medical director may authorize requests for CGM devices requiring prior authorization (Dexcom, MedTronic Guardian).**

**Scope:** **MedStar Family Choice Maryland**

**Policy:** **MFC has formulary preferred CGM systems available through the pharmacy benefit which do not required prior authorization (PA). Therefore, MFC has established criteria to evaluate the medical need for requests for CGM systems requiring PA. Nurse utilization management staff, pharmacist, and/or medical director evaluate CGM requests as outlined in the criteria below. Requests that do not specifically meet the criteria may be submitted with supporting medical records, articles from the literature, etc. and will be reviewed by a pharmacist or medical director for a medical exception.**

**Medical Description/Background:**

Continuous Glucose Monitoring (CGM) systems measure and record glucose levels in interstitial fluid on a recurring basis. Most CGM devices use an electrochemical enzymatic sensor inserted subcutaneously to obtain blood glucose (BG) measurements; BG readings are them automatically transmitted to a device-specific receiver or other smart device (e.g., smartphone, smartwatch, etc.). CGM systems provider information about the current BG value and trend BG results over time, helping patients and their caregivers to fine-tune insulin dosing needs. They also significantly decrease the need for fingersticks to check BG levels, although users still need a glucometer and BG measuring supplies for back-up and scenarios like CGM calibration where readings are unavailable.

There are two types of CGM systems: "real time" and "intermittent scanning." "Real time" CGMs (Dexcom G6/G7 systems; FreeStyle Libre 3; MedTronic Guardian) measure and transmit BG readings every 1-5 minutes and alert the user to out-of-range results. The immediate feedback allows for timely intervention for low/decreasing BG levels and can help prevent serious hypoglycemic and hyperglycemic events. The Dexcom and MedTronic Guardian CGM systems can be linked to specific insulin pump delivery systems, so insulin delivery amount automatically adjusts to BG readings. "Intermittent scanning" CGMs (FreeStyle Libre 14-day; FreeStyle Libre 2) measure BG every minute and capture measurements in 15-minute intervals; the user swipes a reader over the sensor/transmitter to review recent BG readings. Certain "intermittent scanning" models (FreeStyle Libre 2) provide real-time alarms for out-of-range results. Currently there are no FreeStyle Libre CGM systems that link with insulin pumps.

CGM systems are worn episodically or continuously to monitor direct changes in diabetes management. CGM is designed to be used as an adjunct to standard care as 1) providing personal CGM for long-term use; 2) integrating with an insulin pump; or 3) providing professional CGM for short term use. All approaches provide the members with actionable information about their glucose level and trends. Capturing glucose trends continuously via a CGM system can help prescribers and members make informed decisions about dietary choices, physical activity, and medications. CGMs with available alerts and alarms can reduce incidences of impending glycemic events, such as hypoglycemia or hyperglycemia.

To enhance adherence to CGM and minimize resources needed to educate users, it is recommended that beneficiaries be continued on a CGM that they are familiar with when switching from one plan to another. MFC will not change a CGM when Members change among the MCP or FFS program.

**CGM Limitations, Formulary Options, PA Criteria, and Prescribing Information:**

A. Limitations:
   a. CGM systems will only be approved for their FDA indications for use.
   b. Devices under warranty are not a covered benefit and are the liability of the manufacturer.

B. FreeStyle Libre CGM systems and components (readers and sensors) are formulary preferred and available to MFC-members without Prior Authorization (PA).
   a. "Intermittent Scanning" CGM – NO PA REQUIRED: FreeStyle Libre 14-day, FreeStyle Libre 2
      i. FreeStyle Libre 2 is the preferred "Intermittent Scanning" CGM system.
      ii. FreeStyle Libre 14-day system can be continued for members already utilizing this CGM system.
   b. "Real Time" CGM – NO PA REQUIRED: FreeStyle Libre 3
      i. Should be utilized for members where "Real Time" blood glucose monitoring is warranted unless there is a clinical need for a "Real Time" CGM system with additional functionality (e.g. insulin pump interconnectivity, age 2-3 years old).
      ii. Requires a device compatible with the FreeStyle Libre 3 app (runs on Apple iOS and Android smart devices).

C. Prior Authorization (PA) is needed for other "Real Time" CGM systems (Dexcom, MedTronic Guardian) to confirm medical necessity.
   a. The requesting provider must submit a PA request form and include relevant clinical documentation, including:
      i. Confirmed diabetes diagnosis.
      ii. Clinical documentation from most recent office visit for diabetes management (within previous 3 months).
      iii. Current diabetes medication regimen including ≥1 daily insulin injections.
      iv. Recent HbA1c (within previous 3 months).
      v. An established member/healthcare practitioner relationship for diabetes management.
      vi. Confirmed or planned completion of CGM system device training.
      vii. Explanation of clinical need to use the requested CGM system instead of a formulary-preferred option. Possible reasons may include, but are not limited to:
         1. Request for continued use (see next section).
         2. Concurrent use of an insulin pump device with CGM interconnectivity.
         3. Smart device that is compatible with FreeStyle Libre 3 CGM system is unavailable; and/or
         4. CGM is ordered for a member that is 2-3 years old.
   b. Continued use requires yearly PA request reauthorization, and must include:
      i. PA request submitted by the healthcare practitioner managing their diabetes with updated clinical information to support ongoing medical need (within previous 3 months).
      ii. Recent HbA1c (within previous 3 months); and
      iii. Member CGM logs for at least a one-month lookback period that demonstrates the member consistently utilizes their CGM device.
         1. Reports drawn from the CGM to be submitted
         2. Consistent device use is indicated by CGM utilization ≥70% of the total time frame reviewed.

D. Prescribing Information:
   a. Formulary-preferred FreeStyle Libre systems are available to MFC members through the pharmacy benefit without PA.

i. Submit prescriptions to the member's preferred in-network outpatient pharmacy.
ii. Quantity Limits: 1 reader every year, 6 sensors every 84 days (2/month).

b. "Real Time" CGM systems requiring PA:
   i. Dexcom systems can be obtained through the pharmacy benefit OR through the medical benefit.
      1. PA approval is required to receive a Dexcom CGM system through either the pharmacy or medical benefit (See Table 1 for HCPCS codes for CGM submitted as DME).
      2. Pharmacy benefit process:
         a. Send prescriptions for the CGM system to the member's preferred in-network outpatient pharmacy.
         b. Quantity Limits: 1 receiver every year, 1 transmitter every 90 days (if applicable), 9 sensors every 84 days (3/month).
      3. Medical benefit process:
         a. Send CGM orders to an in-network DME supplier.
         b. Quantity Limits: 1 receiver every year, 1 transmitter every 90 days (if applicable), 9 sensors every 84 days (3/month).
   ii. All other "Real Time" CGMs (e.g.: Medtronic) are approved through the medical benefit only and must be sent to a DME supplier for fulfillment.
      1. Submit a non-pharmacy PA Form to MFC (See Table 1 for HCPCS codes for CGM).
      2. Include clinical documentation to support medical necessity.
      3. Send orders for the CGM system to an in-network DME supplier.
      4. Quantity limits: 1 transmitter per year, 12 sensors every 84 days (4/month).

HCPCS Codes for Medical Benefit

**DME HCPCS CODES**

| HCPCS CODES | Description | DEXCOM | MEDTRONIC |
|---|---|---|---|
| E2102 | Adjunctive, non-implanted continuous glucose monitor or receiver | X | X |
| A4238 | Supply allowance for adjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service | X | X |

**References:**

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Dexcom G6 Continuous Glucose Monitoring (CGM) system prescribing information. Available at: https://provider.dexcom.com/education-research/clinic-resources/dexcom-g6-prescribing-information. Accessed 31 March 2023.

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Wright, E.E., Morgan, K., Fu, D.K., Wilkens, N., & Guffey, W.J. (2020) Time in Range: How to Measure It, How to Report It, and Its Practical Application in Clinical Decision-Making. Clinical Diabetes, 38(5): 439-448.

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| **Summary of Changes:** | **5/23**<br>• Updated Regulatory References to ADA 2023 Standards, AACE Consensus Statement updated 2023<br>• **Responsible Parties changed to Health Plan Pharmacist**<br>• **Updated Approved by to: Dr. Wills and C. Attia**<br>• Updated Background information<br>• Added section about FreeStyle Libre (formulary preferred, no PA required)<br>• Updated PA approval criteria for CGM systems with PA requirements (Dexcom, MedTronic) to align with 2023 ADA, AACE recommendations for CGM use<br>• Added new CGM systems models – FreeStyle Libre 3, Dexcom G7<br>• Updated References<br>**2/23**<br>• Codes removed from this policy in accordance with MDH removing these codes from the DMS.DME.OXYGEN Fee Schedule 2023 – A9276, A9277, A9278, K0553 and K0554<br>• Addition of E2102 and A4238 in accordance with MDH adding these codes to the DMS.DME.OXYGEN Fee Schedule 2023<br>• Removed Theresa Bittle (VP Clinical Care and Quality) and Patryce Toye (Chief Medical Officer |

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| | • Added Carol Attia (VP Clinical Care and Quality) and Karyn Wills (Chief Medical Officer)<br>**07/22**<br>• Responsible Parties changed to Dr. Gregory Dohmeier<br>• Removed from Responsible Parties: Dr. Gerry and Dr. Toye<br>Updated Regulatory Reference<br>**11/21:**<br>• FreeStyle Libre details and authorization processes removed as PA was removed on 11/1/2021. Statement to reflect no PA necessary was added.<br>• Removed Professional short-term CGM section (placement of professional grade CGM in physician office) as this practice is used infrequently due to wide availability of CGM technology.<br>• General editing to improved readability.<br>• Corrected Guardian Connect age from 7 and up to 14-75.<br>**7/21:**<br>• New Policy.<br>• Previously known as Non-Pharmacy Policy 1405. |