MedStar Family Choice DISTRICT OF COLUMBIA		
ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**221.DC**	
Subject:	**Continuous Glucose Monitoring Devices**	
Section:	**Pharmacy**	
Initial Effective Date:	**07/01/2021**	
Revision Effective Date(s):	**07/22, 05/23**	
Review Effective 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, AACE Consensus Statement on comprehensive DM2 management – 2023 update DHCF Informational Bulletin 7/12/2022 (CGM) Criteria**	
Approved:	**Sharon Henry, RN Director, Clinical Operations**	**Raymond Tu, MD Senior Medical Director (CMO)**

Purpose: **To describe the current continuous glucose monitoring (CGM) device systems available for MedStar Family Choice, District of Columbia (MFC-DC) enrollees, CGM procurement processes, and to define the conditions under which MFC-DC Clinical Operations staff, pharmacist, or medical directors may authorize requests for CGM devices requiring prior authorization (Dexcom, MedTronic Guardian).**

Scope: **MedStar Family Choice, District Columbia**

Policy: **MFC-DC has formulary-preferred CGM systems available through the pharmacy benefit which do not require prior authorization (PA). Therefore, MFC-DC has established specific criteria to evaluate the medical need for requests for CGM systems requiring PA. Clinical Operations staff, pharmacist, and medical directors evaluate CGM requests as outlined 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 to consider for a medical exception.**

<u>Continuous Glucose Monitoring (CGM) Background:</u>

Continuous Glucose Monitoring (CGM) systems measure glucose content of 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 then automatically transmitted to a device-specific receiver or other smart device (e.g. smartphone, smartwatch, etc.). CGM systems provide 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 by 1) providing personal CGM for long-term use; 2) integrating with an insulin pump; or 3) providing professional CGM for short-term use. All three approaches provide the enrollee with actionable information about their glucose level and trends. Capturing glucose trends continuously via a CGM system can help prescribers and enrollees 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 enrollees be continued on a CGM they are familiar with when switching from one plan to another. MFC-DC will not change a CGM when enrollees 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-DC enrollees without Prior Authorization (PA).
    a. "Intermittent Scanning" CGM: 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 enrollees already utilizing this CGM system.

b. "Real Time" CGM – NO PA REQUIRED: FreeStyle Libre 3
i. Should be utilized for enrollees 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 enrollee/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 enrollee 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. Enrollee CGM logs for at least a one-month lookback period that demonstrates the enrollee 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-DC enrollees through the pharmacy benefit without PA.
i. Submit prescriptions to the enrollee'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 enrollee'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 (eg: 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-DC (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).

Table 1. HCPCS Codes for Medical Benefit

HCPCS CODES	Description	DEXCOM	MEDTRONIC
E2102	Adjunctive, non-implanted CGM or receiver	X	X
A4238	Adjunctive, nonimplanted CGM, includes all supplies and accessories, 1 month supply = 1 unit of service	X	X
K0553	Therapeutic CGM supply allowance, includes all supplies & access. 1 month supply = 1 unit	X	
K0554	Therapeutic CGM receiver/monitor	X	

References:

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Summary of Changes:	**05/23** • Updated Regulatory References to ADA 2023 Standards, AACE Consensus Statement updated 2023 • Added section about FreeStyle Libre (formulary preferred, no PA required) • Updated PA approval criteria for CGM systems with PA requirements (Dexcom, MedTronic) to align with 2023 ADA, AACE recommendations for CGM use • Added new CGM systems models – FreeStyle Libre 3, Dexcom G7

	09/22 • Included DHCF Informational Bulletin 7/12/2022 (CGM) Clinical Criteria on changing CGM devices. **07/22:** • Updated Responsible Parties to Plan Pharmacist. • Changed Approved from Patrice Toye, MD CMO to Raymond Tu, MD Senior Medical Director (CMO). • Updated Regulatory Reference to ADA 2022 Standards • Remove references to authorization and reauthorization criteria for FreeStyle Libre to reflect previous decision to remove PA on Nov. 1, 2021. **7/21:** • New Policy • Previously known as Non-Pharmacy Policy 1405.DC