MedStar Family Choice

ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1405**	
Subject:	**Continuous Glucose Monitoring Devices**	
Section:	**Care Management**	
Initial Effective Date:	**12/01/2012**	
Revision Effective Date(s):	**07/18**	
Historical Revision Date(s):	**10/13, 10/14, 10/15, 07/17**	
Review Effective Date(s):		
Historical Review Date(s):	**10/16**	
Responsible Parties:	**Patryce Toye, MD**	
Responsible Department(s):	**Utilization Management**	
Regulatory References:	**2018 ADA Standards of Medical Care in Diabetes, AACE 2010 Statement on the Use of Continuous Glucose Monitors, AACE/ACE 2016 Outpatient Glucose Monitoring Consensus Statement Endocr. Pract. 2010; 16 (No. 5)**	
Approved:		
	Theresa Bittle, RN **AVP Clinical Operations**	**Patryce A. Toye, MD** **Chief Medical Officer**

Purpose: **It is the purpose of this policy to define the conditions under which MedStar Family Choice utilization staff may authorize continuous glucose monitoring devices.**

Scope: **MedStar Family Choice, MD**

Policy: **It is the policy of MedStar Family Choice (MFC) to authorize continuous glucose monitoring devices by nurse utilization management staff 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 Medical Director for a medical exception.**

A. Medical Description/Background:
Continuous Glucose Monitoring (CGM) systems measure and record glucose levels in interstitial fluid. The stored data depicts trends in glucose measurements. CGM systems consist of three parts: sensor, transmitter, and receiver. The sensor measures glucose levels just underneath the skin. The sensor is typically placed on the abdomen and can last from 6-10 days before replacement depending on purpose and manufacturer. The transmitter sits on top of the sensor and sends data wirelessly to the receiver (monitor) or directly to an insulin pump. The monitor displays the reading, the

speed and direction of the glucose trend, and high/low alerts for notification when blood glucose (BG) is moving out of targeted range.

On September 27, 2017, the U.S. Food and Drug Administration (FDA) approved the use of the Dexcom G6 integrated continuous glucose monitoring (iCGM) system designed to be used with compatible devices. Unlike the G5, the latest Dexcom G6 version is factory calibrated and does not require users to calibrate to ensure accuracy.

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) Personal CGM for long-term use; 2) by integrating with an insulin pump; or 3) professional CGM for short term use.

B. MedStar Family Choice Considers CGMs Medically Necessary for the Following Indications:
    1. Personal CGM for Long-term Use:
        a. Long-term use of CGM devices as an adjunct to standard care, when necessary to detect trends and patterns in glucose levels over time in order to optimize glycimic control and reduce incidences of hyperglycemia and hypoglycemia is considered medically necessary for the following:
            i. Members with type 1 diabetes (including members who are pregnant or desire to become pregnant) and in selected Members with type 2 diabetes meeting criteria as stated in 2018 ADA Standards of Medical Care in Diabetes (on intensive insulin therapy with uncontrolled diabetes unresponsive to conventional insulin dose adjustments); and
        b. When all of the following criteria are met:
            i. The device must be prescribed by an endocrinologist or practitioner who specializes in the treatment of diabetes and is familiar with the management of diabetes using the data obtained from the CGM.
            ii. Recent office note including history and physical, medications, recent HbA1c and other pertinent labs, insulin regimen and/or use of insulin pump.
            iii. The members HbA1c is greater than target, episodes of hyperglycemia or diabetic ketoacidosis in spite of aggressive management and multiple adjustments in insulin regimen.
            iv. Documented recurring episodes of hypoglycemia (<54mg/dl), hypoglycemic seizures, nocturnal hypoglycemia or hypoglycemia unawareness.
            v. Compliance to treatment regimen is demonstrated by monitoring logs (showing glucose testing at least 3-4x per day) maintained for at least two months prior to request.
            vi. Insulin injections are required three or more times per day or an insulin pump is used for maintenance of blood sugar control.
            vii. Perform finger sticks if needed to calibrate the CGM or if symptoms do not match blood glucose reading.
            viii. The member has been instructed by a health care professional in the management of diabetes and/or participated in a diabetes self management education prior to request.
            ix. The member (parent or caregiver if member is a child) must have the ability to understand the technology and willingness to use the CGM (i.e. hear alarms, read and interpret glucose data), and can take action based on the data interpretation.
            x. Certificate of Medical Necessity/Prescription:
                1. Requesting provider's name, contact information and signature.
                2. Prescription: Items requested including type of CGM with description, HCPC codes and quantities.
                3. Demographics.

4. Frequency of insulin injections or pump usage.
5. Frequency of daily glucose testing and blood glucose range.
6. Recent HbA1c.
7. Diagnosis Code.
8. Diabetes Complications.
9. Clinical Indications to support Medical Necessity.

C. Request for Continued CGM Use Requires A Yearly Authorization Request:
   1. Continuation of CGM device as an adjunct to standard care is considered medically necessary for the following:
      a. Member meets all of the above criteria which includes a new Certificate of Medical Necessity (CMN) and updated clinical information to support medical necessity from an endocrinologist or a practitioner specializing in diabetes; and,
      b. Downloaded CGMS logs for one month demonstrating the member is utilizing the CGM on a daily basis.

D. Limitations:
   1. Long term CGM use is not recommended for the treatment of those with Type 2 diabetes or gestational diabetes who are not on intensive insulin therapy.

   2. CGM device must be ordered through a MFC participating DME provider. Devices under warranty that require replacement are not a covered benefit.

   3. CGM systems that are not approved by the FDA are not covered.

   4. The American Diabetes Association recommends robust diabetes education, training and support for optimal CGM implementation and ongoing use for the pediatric population.

   5. The DexCom G5 & G6 CGM is FDA approved for patient's ages 2 and older. The DexCom G4 Platinum (pediatric) is FDA approved for patient's ages 2-17 years. The MiniMed 670G hybrid closed-loop system which alters insulin delivery based on CGM data is FDA approved for children > 14 years of age.

   6. Devices under warranty are not a covered benefit and are the liability of the manufacturer.

E. Professional CGM for Short-Term Use:
   1. Short--term use of continuous glucose monitoring devices as an adjunct to standard care when necessary to provide diagnostic data to the prescribing practitioner is considered medically necessary for the following:
      a. Members with type 1 and type 2 diabetes who have uncontrolled blood glucose levels unresponsive to conventional insulin dose adjustment; and
      b. When all of the following criteria are met:
         i. When necessary to detect trends and patterns in glucose levels to optimize glycimic control and reduce incidences of hyperglycemia and hypoglycemia.
         ii. Recent episode of hospitalization for significant diabetic ketoacidosis or uncontrolled hyperglycemia.
         iii. To facilitate therapy adjustments.

iv. Professional CGM for short-term use is to be prescribed by an endocrinologist or practitioner who specializes in the treatment of diabetes and who is familiar with diabetes management using the data obtained from the CGM.
v. It is anticipated that the device would be used no more than two times in a given 12 month period to give an opportunity for treatment modification. Any additional requests will require review and approval of a Physician Advisor.

2. Information Required for Professional (short-term) CGM Review:
    a. Authorization Request (can use the Maryland Uniform Consultation Referral Form available at www.medstarfamilychoice.com).
        i. Patient Information
        ii. Requesting provider's name, contact information and signature.
        iii. Consultant/Facility Provider (refer to provider's name, location and contact information).
        iv. Referral Information including the following: reason for referral, brief history, diagnosis codes, and HCPC (Procedure) codes. Please note if history of hypoglycemia, hypoglycemia unawareness, nocturnal hypoglycemia.
        v. Place and Date of Service.
        vi. Signature.

3. Recent office note including history and physical, medications, recent HbA1c and other pertinent labs, type and amount of insulin or insulin pump used.

F. Intermittent Scanned CGM Device:
1. Background:

    On September 27, 2017, the U.S. Food and Drug Administration approved the FreeStyle Libre Flash Glucose Monitoring System. It is the first continuous glucose monitoring system that can be used by adult patients to make diabetes treatment decisions without calibration. The device does not communicate continuously, only on demand by waving/scanning a dedicated mobile reader above the sensor wire which is inserted below the skin's surface for up to 10 days. The device is similar to a tracking and trending CGM, designed to detect glucose in interstitial fluid, however it does not automatically send these measurements to a display device and does not provide real-time alerts like a "conventional" CGM for hypoglycemia and hyperglycemic excursions.

    According to the 2018 ADA Standards of Medical Care in Diabetes, more discussion is needed on outcomes and regarding specific recommendations due to significant differences between flash CGM and other CGM devices.

2. Intermittent Scanned CGM device will be evaluated on a case-by-case basis. Submitted clinical documentation will be reviewed for appropriateness of device and/or need for redirection.

G. Information Required for Intermittent Scanned CGM Review:
1. Authorization Request (can use the Maryland Uniform Consultation Referral Form available at www.medstarfamilychoice.com)
    a. Patient Information
    b. Requesting provider's name, contact information and signature
    c. Consultant/Facility Provider (refer to provider's name, location and contact information)

d. Referral Information including the following: reason for referral, brief history, diagnosis codes, and HCPC (Procedure) codes. Please note history of SBGM and/or reasons for not testing.
e. Place and Date of Service
f. Signature

2. Recent office note including history and physical, medications, recent HbA1c and other pertinent labs, type and amount of insulin.
3. Prescribed by an Endocrinologist or practitioner who specializes in diabetes with evidence of a face to face visit within the past 3 months.
4. Member has the ability to understand the technology and willingness to use the intermittent CGM device.
5. Documentation that member has been educated on device
6. Documentation that the member has been using a blood glucose monitor and performing frequent (4 or more times a day) testing.

H. Limitations:

1. Freestyle Libre is not indicated for those 17 or younger, pregnant women or persons on dialysis.

2. Cannot be used for those with hypoglycemia unawareness or intensive insulin therapy with documented hypoglycemia.

3. It is a pharmacy benefit- Available by prescription form these pharmacies: Walgreens, CVS, Wal-Mart and Rite Aid pharmacies.

4. Not processed as a DME.

5. Cannot be used in persons on hemodialysis or pregnant women.

6. Not to be used in anyone with other implanted medical devices (pacemakers, ICDs, etc).

7. Results may be inaccurate in persons with high levels of ascorbic acid (Vit C), salicylic acid (aspirin), dehydration or volume overload. Therefore this system may not be approved in persons taking ascorbic acid or aspirin or persons with a history of repeated dehydration or volume overload.

8. Devices under warranty are not a covered benefit and are the liability of the manufacturer.

9. MFC will provide a reader a maximum of once every three years.

References:

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American Diabetes Association. Standards of Medical Care in Diabetes-2018. Diabetes Care 2018; 41(Suppl. 1):S4-S141.

Blevins TC. Professional Continuous Glucose Monitoring in Clinical Practice 2010. J Diabetes Sci Technol. 2010: 4(2):440-456.

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U.S Food and Drug Administration (FDA). FDA News Release: FDA Authorizes First Fully Interoperable Continuous Glucose Monitoring System, Streamlines Review Pathway for Similar Devices. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm602870.htm . Accessed 06/10/18

U.S Food and Drug Administration (FDA). FDA News Release: FDA approves first continuous glucose monitoring system for adults not requiring blood sample calibration. Available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577890.htm . Accessed 06/10/18

Summary of Changes:	**07/18:** • Removed references to DC health plans • Updated references • Added information on Intermittent Scanned CGM Device • Modified Effective Date to Initial Effective Dates; added Historical Revision Dates and Revision Effective Dates; and added Historical Review Dates and Review Effective Dates. **07/17:** • Changed "Physician Advisor" to "Medical Director" • Changed Carol Attia to Theresa Bittle and updated Dr. Patryce Toye's title from Senior Medical Director to Chief Medical Officer Updated indications for continuous glucose monitoring per FDA 2016 statement • Updated information per 2017 ADA Guideline and AACE/ACE 2016 Outpatient Glucose Monitoring Consensus Statement **10/16:** • No significant changes **10/15:** • Dates and Names updated • Updated to clarify information required from provider and when RN can approve without sending to PA. • Added DexCom G5 to list of pediatric devices