MedStar Family Choice		
ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1405**	
Subject:	**Continuous Glucose Monitoring Devices**	
Section:	**Care Management**	
Effective Date:	**12/01/2012**	
Revision Date(s):	**10/13, 10/14, 10/15**	
Review Date(s):	**10/16**	
Responsible Parties:	**Patryce Toye, MD**	
Responsible Department(s):	**Utilization Management**	
Regulatory References:	**2015 ADA Guideline** **AACE 2010 Statement on the Use of Continuous Glucose Monitors**	
Approved:		
	Carol Attia, RN **AVP, Care Management**	**Patryce A. Toye, MD** **Senior Medical Director**

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; MedStar Family Choice, District of Columbia Healthy Families and Alliance.**

Policy: **It is the policy of MSFC 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 Physician Advisor for a medical exception.**

For the sake of this policy "inadequate glycemic control" is defined as a persistent hyperglycemia (>180mg/dl), HbA1C > 7%, and/or documented recurring episodes of significant hypoglycemia (<50mg/dl), hypoglycemic seizures, hypoglycemia unawareness, or nocturnal hypoglycemia in spite of compliance with multiple alterations in self-monitoring and insulin administration regimens to optimize care as directed by a physician who specializes in the treatment of diabetes.

Medical Description/Background:

Continuous Glucose Monitoring (CGM) systems measure and record glucose levels in interstitial fluid and produce and store data that shows 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 3-7 days before replacement, depending on purpose and manufacturer[i].[ii] 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 BGs are moving out of targeted range. All CGM systems require "calibrations' to ensure accuracy. To calibrate, test the blood glucose by finger-stick and enter the reading into the monitor. The minimum number of calibrations required is once every 12 hours.

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) professional CGM for short term use; 2) Personal CGM for long-term use or 3) by integrating with an insulin pump. CGM does not replace the need for regular blood glucose (BG) testing.

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

I. Professional CGM for Short-term Use

MFC considers this a short term, diagnostic use of this device. This device supplies retrospective data to the prescribing practitioner ('blinded') and/or real-time data to the patient ("unblinded"). The stored data is retrieved and evaluated for widely varying glucose readings that may be missed by intermittent measurements.

MFC utilization staff may authorize for up to 3-7 days use of Continuous Glucose Monitoring (CGM) for members with diabetes who have uncontrolled blood glucose levels unresponsive to conventional insulin dose adjustment and meet criteria in sections A, B, C, and D below:

A. MFC will authorize Professional CGM for short-term use as an adjunct to standard care for patients with type 1 diabetes, type 2, or gestational diabetes who meet **at least two** of the following criteria[iii]:
    1. The patient exhibits inadequate glycemic control despite adjustments in insulin regimen and frequent monitoring of blood glucose with a home glucometer
    2. The patient has had at least one recent episode of hospitalization for significant diabetic ketoacidosis or uncontrolled hyperglycemia.
    3. The patient has signs and symptoms of documented hypoglycemia, hypoglycemic seizures, hypoglycemia unawareness or nocturnal hypoglycemia.
    4. The patient has unexplained large fluctuations in blood glucose values.
    5. The patient is experimenting with important changes to their diabetes treatment regimen (requires consultative review with a Physician Advisor.)
B. And all of the following criteria are also met:

1. 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 how to manage treatment of the person with diabetes based on the data obtained from the CGM.
2. Adherence to a treatment regimen ordered by an Endocrinologist or practitioner specializing in diabetes including:
    a. Frequent blood glucose monitoring (at least 3-4 times a day) as evidenced by monitoring logs
    b. Multiple daily insulin injections (MDI) at least 3 or more injections per day or proper use of an insulin pump
3. The patient must be willing to keep a log of dietary intake, insulin, and Self Monitoring Blood Glucose (SMBG) results[iv]
4. It is anticipated that the device would be used no more than two times in a given year to give an opportunity for treatment modification. Any additional requests will require review and approval of a Physician Advisor.

II. Information Required for Professional (short-term) CGM Review

A. Authorization Request (can use the Maryland Uniform Consultation Referral Form available at www.medstarfamilychoice.com)
    1. Patient Information
    2. Requesting provider's name, contact information and signature
    3. Consultant/Facility Provider (refer to provider's name location and contact information).
    4. Referral Information including: Reason for referral, brief history, diagnosis codes, and HCPC (Procedure) codes. Please note if history of hypoglycemia, hypoglycemia unawareness, nocturnal hypoglycemia
    5. Place of Service
    6. Signature

B. Blood Glucose Log demonstrating frequent blood glucose testing 3-4 times a day for 30 days prior to request.

C. Recent Office Note including History and Physical; Medications; recent HbA1c and other pertinent labs; and type and amount of insulin or insulin pump used.

D. Verification that patient or caregiver is willing to keep a food, insulin, and blood glucose log to aid in adjustment in treatment regimen

E. Verification that patient or caregiver has the ability to understand the technology and is willing to use the monitor (i.e. hear alarms, read and interpret glucose data, and can take action based on the data interpretation)

F. Verification that the patient or caregiver has participated in Diabetes Self-Management or is willing to participate.

III. Personal CGM for Long-term Use

MFC considers this long-term monitoring and a therapeutic use of this device. The device reports data to the member in real time. Data can also be viewed retrospectively by the practitioner through a variety of reports. Personal CGM for long-term use is used

as a supplement to self-monitoring of blood glucose (when it is medically necessary to detect trends and patterns in glucose levels over time in order to optimize glycemic control and reduce incidences of hyperglycemia and hypoglycemia.

MFC considers Personal CGM for long-term use for patients with type 1 diabetes (age 25 years or greater) with uncontrolled diabetes unresponsive to conventional insulin dose adjustment and meet criteria in sections A and B below:

A. MFC utilization staff may authorize Personal CGM for long-term use when one of the following criteria is met:
    1. "Inadequate glycemic control" as evidenced by HbA1c greater than target, episodes of hyperglycemia or diabetic ketoacidosis in spite of aggressive management and multiple adjustments in insulin regimen.
    2. Documented recurring episodes of hypoglycemia (50mg/dl), hypoglycemic seizures, nocturnal hypoglycemia or hypoglycemia unawareness.
    3. During preconception and pregnancy
B. And all of the following criteria are also met:
    1. Personal CGM for long-term use is to be prescribed by an Endocrinologist or practitioner who specializes in the treatment of diabetes and who is familiar with how to manage treatment of the person with diabetes based on the data obtained from the CGM.
    2. It is prescribed by the treating physician to supplement, and not replace, the traditional finger stick self-monitoring of glucose levels. (Finger sticks are still needed to confirm lows/highs and for treatment. Treatment should not be based on CGM reading).
    3. Adherence to a treatment regimen ordered by an Endocrinologist or practitioner specializing in diabetes including:
        a. Frequent blood glucose monitoring (at least 3-4 x day) as evidenced by monitoring logs
        b. Multiple daily insulin injections (MDI) at least 3 or more injections per day or proper use of an insulin pump
    4. 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.
    5. The member has participated in Diabetes Self-Management Education within 6 months prior to request.
    6. The patient is in an appropriate Case Management Program. DM Case Management will assess individual readiness and understanding of CGM use. Will assess and review diabetes education for optimal CGM implementation/benefits and ongoing use.

IV. Limitations:

A. Use of Personal CGM for long-term use is not recommended for the treatment of people with Type 2 diabetes, or gestational diabetes. There is insufficient evidence that the Personal CGM for long-term use leads to improvement of glycemic

control in patients with type 2 or gestational diabetes. Requests will require review by a Physician Advisor.

B. Use of CGM is not recommended for persons with Type 1 diabetes under the age of 25 years old. CGM used in < 25 years (children, teens and adults) did not result in significant HbA1c lowering or difference in hypoglycemia[v]Although the evidence for HbA1C lowering from a Personal CGM for long-term use is less strong in children, teens and younger adults, a CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device.

C. The DexCom G5 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. A pivotal clinical study demonstrated that the pediatric CGM was not as accurate as in adults and the ability of the CGM device to alert in the hypoglycemic range (below 70 mg/dl) was "poor" compared to device use in adults. (http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm384495.htm) [vi]. Requests will require review by a Physician Advisor.

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

V. Information Required for Personal (long-term) CGM Review

A. 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

B. Blood Glucose Log demonstrating frequent blood glucose testing 3-4 times a day for at least 60 days prior to request

C. Recent Office Note including History and Physical, Medications, recent HbA1c and other pertinent labs, type and amount of insulin or insulin pump used

D. Verification that patient or caregiver is willing to keep a log of dietary intake, insulin, and SMBG results

E. Verification that patient or caregiver has the ability to understand the technology and is willing to use the monitor (i.e. hear alarms, read and interpret glucose data, and can take action based on the data interpretation)

F. Verification that the patient or caregiver has participated in Diabetes Self-Management.

References:

[i] Medtronic iPro® 2 Professional CGM. Available at: http://professional.medtronicdiabetes.com/ipro2-professional-cgm . Accessed 01/05/2015.

[ii] Dexcom G4 Platinum Professional CGM. Available at: http://dexcom.com/dexcom-g4-platinum-cgm . Accessed January 05, 2015

[iii] American Association of Clinical Endocrinologists (AACE). Statement by the AACE Consensus Panel on continuous glucose monitoring. Sep/Oct 2010. Available at: http://www.aace.com/publications/position-statements . Accessed January 05, 2014.

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

[v] American Diabetes Association. Standards of Medical Care in Diabetes--2015. Diabetes Care 2015;38(Suppl. 1):S4|DOI: 10.2337/dc15-S003

[vi] FDA News Release: FDA approves pediatric use of Dexcom's G4 Platinum continuous glucose monitoring system: Available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm384495.htm

Summary of Changes:	**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