MedStar Family Choice		
ADMINISTRATIVE POLICY AND PROCEDURE		
Policy #:	**1405**	
Subject:	**Continuous Glucose Monitoring Devices**	
Section:	**Medical Non-Pharmacy Protocols**	
Initial Effective Date:	**12/01/2012**	
Revision Effective Date(s):	**07/18, 07/19, 07/20**	
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:	**2020 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**

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.**

Medical Description/Background:

Real-time Continuous Glucose Monitoring (CGM) systems measure and record glucose levels in interstitial fluid. The system automatically transmits continuous data to the user. It depicts trends in glucose measurements to a receiver, smart phone/watch. Viewing glucose trends in real-time can help make informed decisions about dietary choices, physical activity and medications. Available alerts and alarms can reduce incidences of impending glycemic events, such as hypoglycemia, hyperglycemia and increase time in range. (i.e. Dexcom G6 and Medtronic Guardian Connect).

Intermittently Scanned CGM is like a real-time CGM, however it does not communicate continuously, only on demand by waving/scanning a dedicated mobile reader or a smart phone that reveals the glucose levels. The device does not have alarms or alerts in the absence of user-initiated action (scan). The CGM system can only be used by adult patients to make diabetes treatment decisions. (i.e. FreeStyle Libre)

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. All approaches provide the patients with actionable information about their glucose level and trends.

A. Dexcom and Medtronic CGMs.
    1. MedStar Family Choice considers Dexcom and Medtronic CGMs medically necessary for the following indications:
        a. Members with type 1 diabetes (including members who are pregnant or desire to become pregnant); all children and adolescents with type 1 diabetes and in selected members with type 2 diabetes meeting criteria as stated in 2020 ADA Standards of Medical Care in Diabetes (on intensive insulin therapy); and
        b. When all the following criteria are met:
            i. The device is 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. Office note within 3 months 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, they have episodes of hyperglycemia or diabetic ketoacidosis despite aggressive management and multiple adjustments in insulin regimen.
            iv. Documented recurring episodes of hypoglycemia, hypoglycemic seizures, nocturnal hypoglycemia or hypoglycemia unawareness.
            v. Documented adherence to glucose testing or monitoring logs (showing glucose testing at least 3-4x per day) maintained for at least one month prior to request.
            vi. Insulin injections are required three or more times per day, or the patient is on insulin pump therapy.
            vii. The patient has been instructed by a health care professional in the management of diabetes and has or will complete a training/education program prior to initiation of the CGM.
            viii. The patient/caregiver 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 interpretation of the data.
            ix. Member must be able to perform finger sticks if needed to calibrate the CGM or if symptoms do not match blood glucose reading.

    2. Process for Dexcom or Medtronic CGM request for prior authorization after meeting the above criteria (A.1.)
        a. The CGM company (i.e. Dexcom or Medtronic) should fax a request for authorization with supporting documentation to MFC Fax 410-933-2274
            i. Certificate of Medical Necessity must be completed filled out and signed by the prescribing endocrinologist or provider specializing in diabetes.
            ii. Copy of the last one to two office visit notes.

iii. Documented recurring episodes of hypoglycemia, nocturnal hypoglycemia or hypoglycemia unawareness to support medical necessity.
iv. Documented adherence to glucose testing or a 30-day blood glucose log.
v. If approved the device will be provided through MFC DME supplier.

B. FreeStyle Libre CGM
1. MedStar Family Choice considers the FreeStyle Libre CGM medically necessary for the following indications:
a. Members with type I and type 2 diabetes age 18 and older
b. Replacement of blood glucose testing to detect trends and tracking patterns.
c. Assistance in identifying episodes of hyperglycemia and hypoglycemia.
d. Prescribed by an endocrinologist or practitioner managing patient diabetes.
e. Barriers to testing blood glucose level (i.e. CVA with hemiplegia, neuropathy, frequency of testing, multiple insulin injections, etc.)
f. Member has the ability to understand the technology and willingness to use the intermittent CGM device.
g. Member must be able to perform finger stick if symptoms do not match blood glucose reading.

2. Process for FreeStyle Libre CGM request for prior authorization
a. Authorization Request (can use the Pharmacy Authorizations Form available at www.medstarfamilychoice.com). This form must be completely filled out.
b. It is a pharmacy benefit.
c. Recent office note including history and physical, medications, recent HbA1c and other pertinent labs, type and amount of insulin.
d. Prescribed by an Endocrinologist or practitioner managing patient diabetes with evidence of a visit (in person or video) within the past 3 months.
e. Documentation of self-blood glucose monitoring and/or reasons for not testing.

C. Request for Continued CGM Use Requires A Yearly Authorization Request:
1. Continuation of CGM (Dexcom/Medtronic) device is considered medically necessary for the following:
a. Member meets all the above criteria which includes a new Certificate of Medical Necessity (CMN), recent HbA1c 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 daily.

2. Continuation Freestyle Libre-
a. Submit a new Authorization Request (can use the Pharmacy Authorizations Form available at www.medstarfamilychoice.com). This form must be completely filled out.
b. Recent HbA1c and updated clinical information from practitioner managing patient diabetes.

D. Limitations for Dexcom or Medtronic CGMs:
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 systems that are not approved by the FDA are not covered.

3. The standalone Medtronic Guardian Connect CGM system is FDA approved for ages 14 and older.

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

5. The DexCom G6 CGM is FDA approved for patient's ages 2 and older.

6. The MiniMed 670G hybrid closed-loop system which alters insulin delivery based on CGM data (Guardian Sensor 3) is FDA approved for children with T1DM aged 7 and older.

E. Limitations for the Freestyle Libre CGM:
   1. Freestyle Libre is not indicated for those 17 or younger.

   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 from participating pharmacies.

   4. MFC will provide a reader a maximum of once every year.

   5. Cannot be used in persons on hemodialysis, pregnant women or the critically ill population.

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

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

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

F. Indications for Professional CGM use:
   1. Short-term use of continuous glucose monitoring devices 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.
      b. To detect trends and patterns in glucose levels to optimize glycemic control and reduce incidences of hyperglycemia and hypoglycemia.
      c. Recent episode of hospitalization for significant diabetic ketoacidosis or uncontrolled hyperglycemia.
      d. To facilitate therapy adjustments
      e. 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
      f. Facilitate changed lifestyle behaviors.
      g. It is anticipated that the device would be used not 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 Medical Director.

   2. Process 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 and recent HbA1c.
   v. Place and Date of Service.
   vi. Signature.
   vii. Recent office note including history and physical, medications, recent HbA1c and other pertinent labs, type and amount of insulin or insulin pump use.

G. Billing Information and HCPCS Codes:
1. FreeStyle Libre is approved as a Pharmacy benefit only.
   a. FreeStyle Libre 14-day Reader: NDC 57599-0002-00
   b. FreeStyle Libre 14-day Sensor: NDC 57599-0001-01

2. Dexcom and Medtronic are approved as DME:

DME HCPCS CODES

HCPCS CODES	Description	DEXCOM	MEDTRONIC
A9276	Sensor: invasive (e.g. subcutaneous), disposable, for use with interstitial CGM monitoring system	X	X
A9277	Transmitter: external, for use with interstitial CGM	X	X
A9278	Receiver (monitor); external, for use with interstitial CGM	X	X
K0553	Therapeutic CGM supply allowance, includes all supplies & access. 1-month supply= 1 unit	X	
K0554	Therapeutic CGM receiver/monitor	X	

References:

American Diabetes Association. Clinical Implications of Real-time and Intermittently Scanned Continuous Glucose Monitoring. Diabetes Care 2018; https://doi.org/10.2337/dc18-1150

American Diabetes Association. Standards of Medical Care in Diabetes-2020. Diabetes Care 2020; 43(Suppl. 1): S71-S88.

"Consumer guide 2020". Diabetes Forecast Healthy Living Magazine (March/April): 41-.

Dexcom G6 Continuous Glucose Monitoring (CGM) System/Zero Fingersticks. Available at: https://www.dexcom.com/g6-cgm-system. Accessed 06/03/2020

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 06/03/2020

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 6/30/2020

Freestyle Libre 14 Day Flash Glucose Monitoring System. Available at: https://www.fda.gov/medical-devices/recently-approved-devices/freestyle-libre-14-day-flash-glucose-monitoring-system-p160030s017. Accessed 6/03/2020

Summary of Changes:	**07/20:** • Updated Section from Care Management to Medical Non-Pharmacy Protocols. • Reformatted the Policy. • Added indications for medical necessity for the FreeStyle Libre. • Added HCPCS codes. • Updated References. **07/19:** • Removed "Maryland" from scope. • Updated the types of CGM's now available. • Updated the References **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