BENEFIT COVERAGE POLICY

Title: BCP-64 Continuous Glucose Monitors and Supplies

Effective Date: 01/01/2020

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

Health Plan covers continuous glucose monitors and supplies when deemed medically necessary and supported by clinical documentation to meet the criteria below. Continuous glucose monitors and supplies require prior approval for benefit coverage.

For all non-network covered services to be paid at the network benefit level except for emergency/urgent services, prior approval is required.

Refer to member's benefit coverage document for specific benefit description, guidelines, coverage, and exclusions.

2.0 Background:

Continuous glucose monitoring (CGM) is a proposed adjunct to intermittent self-monitoring blood glucose (SMBG). CGM devices provide ongoing, real-time monitoring and recording of glucose levels every one to ten minutes by measurement of interstitial fluid. Interstitial measurements generally lag from three to 20 minutes behind finger-stick values. Therefore, CGM is only to be used with finger-stick blood glucose monitoring.

The continuous glucose monitoring system (CGMS) consists of a monitor (receiver), disposable sensors, and a transmitter. Depending on the device, CGM sensors can be worn from 3 to 7 days before replacing. Some monitors provide real-time information, while others require that data be downloaded and reviewed retrospectively by a physician. This information can guide adjustments to therapy, with the goal of improving overall glycemic control.

3.0 Clinical Determination Guidelines:

A. Professional, intermittent, short-term (72 hours to seven days), diagnostic use of continuous interstitial glucose monitoring devices as an adjunct to standard care is considered medically necessary in individuals with Type I or II diabetes mellitus, when ALL the following criteria are met:

1. Repeated hypoglycemia (less than 50 mg/dl) and hyperglycemia (greater than 150 mg/dl) despite compliance with frequent self-monitoring (at least four times per day) and unresponsive to conventional insulin dose adjustment; and

2. Monitoring and interpretation are under the supervision of a physician; and

3. No more than three continuous glucose monitoring periods for diagnostic use are considered medically necessary within a 12-month period.

B. Personal, long-term (greater than one week), therapeutic use of a continuous interstitial glucose monitoring device is considered medically necessary as an adjunct to finger-stick testing of blood glucose for management of patients with diabetes mellitus requiring insulin. For the initial request, ALL the following criteria must be met:

1. Completion of a diabetes self-management education program; and

2. Attestation the ordering provider will be managing the CGMS; and

3. Treatment program including three or more insulin injections per day or a medically necessary insulin pump is used to maintain blood sugar control; and

4. Documented blood glucose self-testing an average of four or more times per day; and

5. Any of the following while on a multiple daily injection regimen:

   a. Recurring episodes (two or more events) of Level 2 hypoglycemia (less than 54 mg/dl) in any 30-day period while on insulin therapy, including suspected episodes (e.g. nocturnal); or

   b. Impaired awareness or the inability to communicate hypoglycemia.

   c. A1C is greater than 7% within the previous 90 days prior to request.

C. For a replacement monitor, both the following must be met:

1. Attestation that the ordering provider is managing the CGMS, **and**

2. Member must meet with a participating specialist or certified diabetes educator for diabetes self-management education if:

   a. A1C is greater than 7% within the previous 90 days prior to request.

   b. Recurrent hypoglycemia.

   c. Diabetes-related ER or inpatient admission in the 12 months prior to receiving a replacement CGMS device.

3. Coverage limits based on manufacturer's information:

   a. Continuous glucose monitor/receiver – one every three years.

   b. Sensors – maximum of 72 sensors per plan benefit or calendar year.

      Note: Sensors are intended to be changed every four to six days, which would require approximately 72 sensors per year. Due to the CPT descriptor specifying 1 unit = one-day supply, 365 units are approved for a one-year supply. Provider reimbursement for 72 sensors is averaged out for the 365 units.

   c. Transmitters – maximum of two per plan benefit or calendar year.

   d. Consult member's benefit document for coverage of DME replacement.

D. For pregnancy, use of a CGMS is at the discretion of the maternal medicine specialist. For continued use after pregnancy, criteria listed above must be met.

E. Items not covered because each has not demonstrated an improvement in health outcomes and is therefore, considered not medically necessary and/or is a convenience item:

1. Additional software or hardware required for downloading data to a device such as a personal computer, smart phone, or tablet to aid in self-management of diabetes mellitus (e.g., MiniMed Connect).
2. Combination devices that include a home blood glucose monitor combined with a cellular phone or other device not specifically indicated for management of diabetes mellitus (e.g., blood pressure monitor, cholesterol screening analyzer).
3. CGM systems for the following devices, for any indication, as these technologies are considered experimental or investigational:
    a. Fully automated, closed-loop insulin delivery system (e.g., artificial pancreas or bihormonal bionic endocrine pancreas) insulin pumps; or
    b. Implantable interstitial glucose sensors; or
    c. Implantable insulin pumps.
4. Remote glucose monitor device (e.g., mySentry/Medtronic MiniMed, Inc., Dexcom SHARE).
5. Hypoglycemic wristband alarm (e.g., Diabetes Sentry™).
6. Laser Blood Glucose Monitoring device (Lasette™).
7. Implantable glucose sensors (e.g., Eversense, GlySens ICGM system).

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = PPO; 3 = ASO group L0000264; 4 = ASO group L0001269 Non-Union & union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union only.

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Reference**
A9276	Sensor invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply	Y	Benefits and Coverage, Diabetic Supplies, OR Durable Medical Equipment
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system	Y	Benefits and Coverage, Diabetic Supplies, OR Durable Medical Equipment
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system	Y	Benefits and Coverage, Diabetic Supplies, OR Durable Medical Equipment
K0553	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service (includes HCPCS codes E0607, A4233, A4253)	Y	Benefits and Coverage, Diabetic Supplies, OR Durable Medical Equipment
K0554	Receiver (monitor), dedicated, for use with	Y	Benefits and Coverage,

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Reference**
	therapeutic glucose continuous monitor system		Diabetic Supplies, OR Durable Medical Equipment
95249	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; patient-provided equipment, sensor placement, hook-up, calibration of monitor, patient training, and printout of recording	N	Benefits and Coverage, Physician Office Services – Sickness/Injury, OR Professional Fees for Surgical and Medical Services
95250	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; physician or other qualified health care professional (office) provided equipment, sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording	N	Benefits and Coverage, Physician Office Services – Sickness/Injury, OR Professional Fees for Surgical and Medical Services
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report	N	Benefits and Coverage, Physician Office Services – Sickness/Injury, OR Professional Fees for Surgical and Medical Services

ICD-10 DIAGNOSIS CODES	
Code	**Description**
E08.00 – E08.9	Diabetes mellitus due to underlying condition
E09.00 – E09.9	Drug or chemical induced diabetes mellitus
E10.10 – E10.9	Type diabetes mellitus
E11.00 – E11.9	Type 2 diabetes mellitus
E13.00 – E13.9	Other specified diabetes mellitus
O24.410 – O24.439	Diabetes mellitus in pregnancy, childbirth, and puerperium
O99.810 – O99.815	Abnormal glucose complicating pregnancy, childbirth and the puerperium

5.0 Unique Configuration/Prior Approval/Coverage Details:

None.

6.0 Terms & Definitions:

A1C – A blood test that measures average blood glucose over the past two to three months and is the best way to measure overall glucose control. It should be measured two to four times a year with the goal of less than 7%.

Basal insulin – The insulin that controls blood glucose levels between meals and overnight. It controls glucose in the fasting state.

Beta cells – Cells that produce insulin. They are located within the islets of Langerhans in the pancreas.

Blood glucose – A type of sugar that is created when the carbohydrate that one eats is broken down in the body. During digestion, glucose passes through the wall of the intestine into the bloodstream to the liver and eventually into the general circulation. From there glucose can then enter individual cells or tissue throughout the body to be used for fuel and provide energy.

Blood glucose - A blood glucose test measures the amount of a type of sugar, called glucose, in your blood. Glucose comes from carbohydrate foods. It is the main source of energy used by the body.

Carbohydrate – The main source of fuel for the body. Carbohydrates include starches and sugars and are found in bread, pasta, fruits, vegetables, milk, and sweets. Carbs are broken down into a sugar called glucose.

Dawn phenomenon – A rise in blood glucose levels that occurs in the early morning hours.

Gastroparesis – A condition in which neuropathy affects the nerves controlling the digestive tract and causes difficulty processing or disposing of food. It can cause nausea, vomiting, bloating or diarrhea.

Glucose tolerance test – A blood test done every hour or at the two-hour point after drinking a concentrated sugar liquid. This is one test used to diagnosis diabetes. If, at two hours, the blood glucose rises to over 200 mg/dl you have diabetes.

Hyperglycemia – Blood glucose is generally considered “high” when it is 150 mg/dl or above the individual’s blood glucose target.

Hypoglycemia – Blood glucose that is below 50 mg/dl or without symptoms or below 90 mg/dl with symptoms.

Intermediate-acting insulin – A type of insulin that begins to work to lower blood glucose within one to four hours with a peak action of four to 15 hours after injection. These include NPH and lente.

Interstitial fluid glucose – A thin layer of fluid which surrounds the body’s cells. Interstitial fluid glucose measurements lag behind blood glucose monitoring by ten to 25 minutes. The intent of interstitial glucose monitoring is to assist in detection of trends or patterns in glucose levels.

Long-acting peaking – A type of insulin that begins to work four to six hours after injection with a peak action of eight to 30 hours and lasts for 24 to 36 hours. This includes ultralente.

Long-acting peakless – A type of basal insulin that begins working within one ot two hours after injection and lasts for 24 hours. This includes glargine.

Short-acting insulin – A type of insulin that begins working within 30 to 60 minutes and peaks one to five hours after injection. The common form of short-acting insulin is “regular.”

7.0 References, Citations & Resources:

American Diabetes Association (ADA). Clinical practice recommendations. 2010-2015. Available at: http://care.diabetesjournals.org/content/38/Supplement_1/S4.full

American Diabetes A.6. Glycemic Targets: Standards of Medical Care in Diabetes – 2018. Diabetes Care. Jan 2018; 41 (sSuppl1): S55-S64. PMID 29222377

Diabetes technology-continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. Nov 2016;101(11):3922-3937. PMID 27588440 Hayes, Inc. Medical Technology Directory, Continuous Glucose Monitoring Systems, July 31, 2018.

8.0 Associated Documents [For internal use only]:

Standard Operating Procedure (SOP) – MM-03 Benefit Determinations; SOP 007 Algorithm for Use of Criteria for Benefit Determinations.

Sample Letter – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Lack of Information Letter; Partial Coverage; Partial Non-Coverage Letter.

Form – Request Form: Out of Network/Prior Authorization.

9.0 Revision History:

Original Effective Date: 01/01/2016

Last Approval Date: 10/22/2019

Next Review Date: 01/01/2021

Revision Date	Reason for Revision
September 2015	Policy created
February 10, 2016	Title changes – removed references to Medical Resource Management (MRM) and changed to "Medical Policy" with the responsible Dept assigned to Utilization Mgmt team. Removed references to Sparrow PHP, Healthy Michigan, MIChild, and MDHHS. Product Application: added reference to COC definitions related to policy. Clinical Determination Guidelines: A.2. Revised age limit to FDA approved two years and older. D.2. Number of boxes of sensors from one per year to one per month.
February 2017	Annual review revisions – changed from MRM Medical Policy 030 to Benefit Coverage Committee Policy formatting. Removed ICD-9 diagnosis codes, no change in criteria.
May 2017	Revised policy to include long-term continuous glucose monitoring, clarified monitor and supply limits, added services not covered. Effective 7/1/17 new CPT codes added x2.
August 2017	Added bundled monthly supply allowance and added CMS reference.
April 2018	References updated. Clarified policy effective date. Removed bundled monthly supply allowance.
September 2018	Annual review; modified title to include "supplies." Update references. Annual review & approval by QI/MRM 10/10/18.
September 2019	Annual review; criteria updated; to include Type 2 DM requiring insulin, hypoglycemic event parameters added, note added regarding sensor limit, annual review and approval by QI/MRM 10/9/19, approved by BCC 10/21/19.