BENEFIT COVERAGE POLICY

Title: BCP-64 Continuous Glucose Monitors and Supplies

Effective Date: 01/01/2024



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:

The 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 three to seven 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.
- B. Personal, long-term (greater than one week), therapeutic use of a continuous interstitial glucose monitoring device is considered medically necessary when InterQual® criteria are met.

- 1. Coverage limits are based on manufacturer's information:
 - 1. Continuous glucose monitor/receiver one every three years.
 - 2. 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.

- 3. Transmitters maximum of four per plan benefit or calendar year.
- 4. Consult member's benefit document for coverage of DME replacement.
- C. The OmniPod DASH Personal Diabetes Management system (PDM), manufactured by Insulet is a monitor and uses pods for insulin delivery. Insulet provides a free PDM to the patient, once every four years. The pods (HCPCS A9274) come in boxes of 10, each containing 200 units of fast-acting insulin, and lasts up to three days. These do not require prior approval and one box per month is covered under the medical or pharmacy benefit.
- D. For pregnancy, the use of a CGMS is at the discretion of the maternal medicine specialist. For continued use after pregnancy, the criteria listed above must be met.
- E. When requests are for CGM supplies where the receiver was provided by another payer, supplies are approved solely on the CGM policy quantity limit language. Requests for the replacement of a CGM receiver paid for by another payer are reviewed using InterQual® criteria. A new receiver is covered if the criteria are met.
- F. Items are not covered because they have not demonstrated an improvement in health outcomes and therefore, are considered not medically necessary and/or a convenience item and include:
 - 1. Additional software or hardware required for downloading data to a device such as a personal computer, smartphone, 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 L000264; 4 = ASO group L0001269 Non-Union & union; 5 = ASO group L0001631; 6 = ASO group L0002011; 7 = ASO group L0001269 Union only; 8 = ASO group L0002184, 9 = ASO group L0002237; 10 = ASO L0002193.

COVERED CODES			
Code	Description	Prior Approval	Benefit Plan Cost Share Reference
A4239	Supply allowance for nonadjunctive, nonimplanted continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service	Y	Diabetic supplies, OR durable medical equipment
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories	N	Diabetic supplies, OR durable medical equipment
A9276	Sensor invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply	Y	Diabetic supplies, OR durable medical equipment
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system	Y	Diabetic supplies, OR durable medical equipment
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system	Y	Diabetic supplies, OR durable medical equipment
E2103	Nonadjunctive, nonimplanted continuous glucose monitor (CGM) or receiver	Y	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	PCP/specialist visit, professional fees for surgical and medical services OR outpatient diagnostic/therapeutic 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	PCP/specialist visit, professional fees for surgical and medical services OR outpatient diagnostic/therapeutic services
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; analysis, interpretation and report	Ν	PCP/specialist visit, professional fees for surgical and medical services OR outpatient diagnostic/therapeutic services

NON-COVERED CODES		
Code	Description	Benefit Plan Reference/Reason
0740T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; initial	Convenience item

	NON-COVERED CODES		
Code	Description	Benefit Plan Reference/Reason	
	set-up and patient education		
0741T	Remote autonomous algorithm-based recommendation system for insulin dose calculation and titration; provision of software, data collection, transmission, and storage, each 30 days	Convenience item	

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		
O24.011 – O24.93	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:

 $\underline{A1C}$ – 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%.

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

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

<u>Blood glucose</u> – 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 to provide energy.

<u>Blood glucose test</u> - 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.

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

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

<u>Gastroparesis</u> – 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.

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

<u>Hyperglycemia</u> – Blood glucose is generally considered "high" when it is 150 mg/dl or above the individual's blood glucose target.

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

<u>Intermediate-acting insulin</u> – 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.

<u>Interstitial fluid glucose</u> – A thin layer of fluid that 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 the 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.

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

<u>Short-acting insulin</u> – 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:

1. InterQual® 2023, July 2023 Release, CP: Durable Medical Equipment Continuous Glucose Monitors, Insulin Pumps, and Automated Insulin Delivery Technology

8.0 Associated Documents [For internal use only]:

Policies & Procedures (P&P): MMP-09 Benefit Determinations MMP-02 Transition and Continuity of Care; UMPP-02 Peer to Peer Conversations

Standard Operating Procedure (SOP) – MMS-03 Algorithm for Use of Criteria for Benefit Determinations, MMS-45 UM Nurse Review, MMS-52 Inpatient Case Process in CCA; MMS-53 Outpatient Case Process in CCA

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

Form – Request Form: Out of Network/ Prior Authorization

9.0 Revision History:

Original Effective Date: 01/01/2016

Next Review Date: 01/01/2025

Revision Date	Reason for Revision
9/15	Policy created
2/16	Title changes – removed references to Medical Resource Management (MRM) and changed to "Medical Policy" with the responsible Dept assigned to the 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.
2/17	Annual review revisions – changed from MRM Medical Policy 030 to Benefit Coverage Committee Policy formatting. Removed ICD-9 diagnosis codes, no change in criteria.
5/17	Revised policy to include long-term continuous glucose monitoring, clarified monitor and supply limits, and added services not covered. Effective 7/1/17 new CPT codes were added x2.

Revision Date	Reason for Revision	
8/17	Added bundled monthly supply allowance and added CMS reference.	
4/18	References updated. Clarified policy effective date. Removed bundled monthly supply allowance.	
9/18	Annual review: modified title to include "supplies." Update references. Annual review and approval by QI/MRM 10/10/18.	
9/19	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.	
9/20	Annual review replaced internal criteria with InterQual criteria, changed benefit plan reference to cost share type	
2/21	Changed limit on transmitters from 2 to 4 per benefit period	
11/21	Annual review; updated references	
2/22	Off-cycle review requested by K Peters. Added info re: OmniPod Dash. Approved at BCC meeting 03-07-2022	
10/22	Annual review added ASO groups L0002237 and L0002193 to policy and updated InterQual references. Added A9274 to the covered codes section.	
10/23	Annual review. Reformatted and made OmniPod DASH its own letter (C) since it doesn't require criteria; K0553 and K0554 were removed due to being deleted codes as of 1/1/2023; added new 1/1/23 codes A4239 and E2103 to Covered section & 0740T and 0741T to non-covered section; updated InterQual reference and Associated Documents 10/17/23 Gap Analysis updates: updated pregnancy diagnosis code range to O24.011 through O24.93, updated benefit plan/reference reason for codes 95249-51.	