SUBJECT: Continuous Glucose Monitoring and Continuous Glucose Monitoring Systems

Prior approval is required for some or all procedure codes listed in this Corporate Medical Policy.

**Definition:** Continuous glucose monitoring is intended to guide diabetes mellitus management by identifying blood glucose fluctuations that are not detected by intermittent glucose monitoring. The process involves the use of a noninvasive or minimally invasive device, consisting of a sensor, transmitter and receiver. The sensor performs frequent subcutaneous or interstitial fluid glucose measurements. These data are then transmitted and stored for review. The information obtained may identify unrecognized trends and patterns of blood glucose fluctuation that can be improved with modifications of eating habits, medication dosing and exercise routine.

Newer continuous glucose monitoring devices provide real-time glucose measurements for instant viewing. Subcutaneous and interstitial fluid glucose measurements obtained with real-time monitoring are not intended to replace fingerstick blood glucose testing but to alert the individual that a significant fluctuation may be present. These devices are purported to identify clinically significant silent hyperglycemia and hypoglycemia, thus facilitating both acute and long-term insulin therapy management.

**Medical Necessity:**

I. **Short-term continuous glucose monitoring:** The Company considers short-term (72 hours – 7 days) continuous glucose monitoring (CPT Codes 95249, 95250 and 95251) **medically necessary** and eligible for reimbursement providing that all of the following medical criteria are met:

- Diabetes mellitus (Type 1 or 2); and
- Completion of a comprehensive diabetes education program; and
- Multiple, daily insulin injections (≥3) or insulin pump therapy with frequent dosage adjustments for ≥6 months; and
- Monitoring device to be used as an adjunct to standard care; and

- **At least one** of the following:
  1. Frequent unexplained, hypoglycemic episodes; or
  2. Frequent nocturnal hypoglycemia; or
3. Hypoglycemic unawareness; or
4. Dawn phenomenon; or
5. Pregnancy; or
6. Monitoring will be prior to insulin pump therapy to determine basal levels and follow-up to verify adequate glucose levels; or
7. Multiple episodes or repeated hospitalizations for ketoacidosis or hyperglycemia, not due to medication or dietary non-compliance.

The Company considers continuous glucose monitoring (CPT Codes 95249, 95250 and 95251) for all other clinical conditions investigational and not eligible for reimbursement.

**Frequency limitations:** The Company limits the frequency of continuous glucose monitoring (CPT Codes 95249, 95250 and 95251) to two episodes within a 365 day period. Requests for more frequent monitoring will be forwarded to the Chief Medical Officer or specialty matched physician reviewer for review of medical necessity.

**II. Continuous glucose monitoring systems:** The Company considers therapeutic continuous glucose monitoring systems (e.g., FreeStyle Libre® and Dexcom G5®) (HCPCS Codes K0553 and K0554) and non-therapeutic continuous glucose monitoring systems (e.g., DexCom® Continuous Glucose Monitoring System, Guardian® REAL-Time, Paradigm® REAL-Time Systems, FreeStyle Navigator® Continuous Glucose Monitoring System and MiniMed® 530G with Enlite® Sensor, Omnipod® Insulin Management System) (HCPCS Codes A9274, A9276, A9277 and A9278) medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Type 1 diabetes mellitus; and
- Short-term (72 hours – 7 days) continuous glucose monitoring (I) meets all medical criteria listed above (excluding Type 2 diabetes mellitus); and
- Individuals undergoing treatment with external insulin pump therapy are not currently utilizing a functioning continuous glucose monitor and external insulin pump without wireless integration capability.

OR

Continuation of pediatric CGM use (pediatric use of a CGM device in the past 12 months)

**III. Continuous glucose monitoring systems (pediatric):** The Company considers one time approval of pediatric (ages 2 – 17 for Dexcom G5® and ages 8 – 17 for all other monitors) continuous glucose monitoring systems medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Type 1 diabetes mellitus; and
- Device is FDA approved for pediatric use.
• Multiple, daily insulin injections (>3) or insulin pump therapy with frequent dosage adjustments or recurring episodes of severe hypoglycemia (50 mg/dl); and
• Monitoring device to be used as an adjunct to standard care; and
• Individuals undergoing treatment with external insulin pump therapy are not currently utilizing a functioning continuous glucose monitor and external insulin pump without wireless integration capability; and
• Individual must be willing and able to wear and operate the device.

Non-diabetic hypoglycemia: Suspected non-diabetic hypoglycemia, such as may occur with nesidioblastosis (islet cell dysmaturation syndrome) or insulinoma may also qualify for continuous glucose monitoring if above non-diabetic criteria are meet.

NOTE: Equipment replacement is not eligible for reimbursement in instances where it was determined that the equipment was maliciously damaged, neglected, used or misused in a fashion not intended by the manufacturer.

NOTE: The Company allows up to 40 units in 90 days for Omnipods (HCPC A9274).

Specialty limitations: The Company requires a board certified endocrinologist, an internist or a physician specializing in diabetes management (e.g., family practice specialist) to order and interpret continuous glucose monitoring results.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request by the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Prior approval is required for HCPCS Codes A9276, A9277, A9278, K0553 and K0554.
Sources of Information:

- Centers for Medicare & Medicaid Services.

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<td>CPT:</td>
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