Geisinger

Geisinger Health Plan Policies and Procedure Manual

Policy: MP071

Section: Medical Benefit Policy

Subject: Continuous Subcutaneous Glucose Monitor CSGM

I. Policy: Continuous Subcutaneous Glucose Monitor (CSGM)

II. Purpose/Objective:

To provide a policy of coverage regarding Continuous Subcutaneous Glucose Monitor (CSGM)

III. Responsibility:

A. Medical Directors
B. Medical Management

IV. Required Definitions

1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

ALL Durable Medical Equipment provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are **NOT SEPARATELY REIMBURSABLE.**

DESCRIPTION:
Continuous subcutaneous glucose monitors (CSGM) measure and record blood glucose levels in interstitial fluid and produce data that demonstrate trends in glucose measurements. The continuous subcutaneous glucose monitor reads the glucose level every 5 minutes through a subcutaneously implanted sensor attached to a small plastic disk taped to the skin to hold the sensor in place. A thin wire connects the sensor to a pager-sized glucose monitor, which records and stores glucose values in memory. Continuous monitoring is usually performed over a 1-3 day time period, after which, the stored information is retrieved and evaluated. CSGM captures potentially widely varying blood glucose readings that may be missed by intermittent measurements. This additional information is often used to manage the current medication regimen and, ultimately, obtain tighter glycemic control and reduce nocturnal hypoglycemia. Data downloads are available to record compliance with device use as well as glucose trends. Compliance for the purposes of this policy will be defined as use of the monitor 6 or more days per week. Extenuating circumstances that affect compliance will be taken into consideration.

For Commercial, and Medicaid Business Segment:

INDICATIONS:

I. Continuous subcutaneous glucose monitors with a device provided from an endocrinologist office or clinic will be covered for a maximum of 3 consecutive days, twice per calendar year when all of the following criteria are met:

- Medical documentation of a diagnosis of Type 1 diabetes, Type 2 diabetes or gestational diabetes; **and**
- Suspected hypo- (<50mg/dl) and hyperglycemia excursions; **or**
- Suspected episodes of hypoglycemia unawareness including symptoms, consequences, frequency, and patterns identified; **and**
- Poor blood glucose control as evidenced by two HbA1C values greater than 7.0 within previous 6 months

This device is intended for one-time or occasional 1-3 day time period. The devices provided for this service are supplied by the clinician. It is not meant to replace the traditional (fingerstick) self-monitoring measurements, but rather, serve as a short-term adjunct to these measurements.

A maximum of two CGMS monitoring periods are considered medically necessary within a 12-month period.

II. Personal continuous subcutaneous glucose monitor may be considered for pediatric and adult members with diabetes mellitus (Type 1 or 2) treated with insulin who meet all of the following criteria:

1. Documentation of a diagnosis of diabetes; **and**
2. Documentation of daily insulin therapy

The "flash" continuous glucose monitoring system (e.g., Flash Glucose Monitoring System) is considered to be an acceptable alternative to other continuous glucose monitoring systems for medically necessary indications in members 18 years of age and older with diabetes.

The Freestyle Libre device may be considered for members with diabetes mellitus (Type 1 or 2) who meet all of the following criteria:

Age 18 years or older; and at least one of the following:

- Current insulin therapy; or
- Functional barriers to finger stick blood glucose monitoring; or
- History of recurrent hypoglycemic episodes; or
- Medical record documentation of HbA1c of 9 or greater

The Freestyle Libre 2 device may be considered for members with diabetes mellitus (Type 1 or 2) who meet all of the following criteria:

Age 4 year and older and at least one of the following:

- Current insulin therapy; or
- Functional barriers to finger stick blood glucose monitoring; or
- History of recurrent hypoglycemic episodes; or
- Medical record documentation of HbA1c of 9 or greater

FOR MEDICARE BUSINESS SEGMENT:

Per CMS, Therapeutic(non-adjunctive) or non-therapeutic (adjunctive) CGM may be covered by Medicare when all of the following criteria are met:

- The member has diabetes mellitus; and,
- The member is insulin-treated with multiple daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
- The member's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of therapeutic CGM testing results.
- The member is engaged in routine periodic visits with their treating provider for ongoing assessment and management of their diabetes.

The Freestyle Libre device may be considered for members with diabetes mellitus (Type 1 or 2) who meet all of the following criteria:

Age 18 years or older; and at least one of the following:

- Current insulin therapy; or
- Functional barriers to finger stick blood glucose monitoring; or
- History of recurrent hypoglycemic episodes; or
- Medical record documentation of HbA1c of 9 or greater

Please see: Local Coverage Determination (LCD): Glucose Monitors (L33822) Noridian Healthcare Solutions, LLC (16013 - DME MAC, J-A) https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=33822 and Glucose Monitor - Policy Article (A52464) https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52464

Documentation of a vendor certificate of medical necessity with physician signature without previous supporting documentation in the medical record is not sufficient to meet criteria for coverage.

AUTHORIZATION DETERMINATION Long-term use of continuous glucose monitoring devices will be initially provided for a three month time period. Members authorized to receive long-term use of continuous glucose monitoring devices must be followed by a Plan disease management or medical home case manager. At the end of the first three months, Health Plan staff will review compliance and health outcomes data provided by the ordering physician. Non-compliance or lack of improvement in glycemic control will result in medical director review to determine continued medical necessity. Extenuating circumstances that affect compliance will be taken into consideration.

EXCLUSIONS:

The GlucoWatch® is an external device worn like a wristwatch that measures glucose every 20 minutes in interstitial fluid extracted through the skin with an electric current (referred to as reverse iontophoresis). Use of a non-implanted, external device (e.g., GlucoWatch®) in the monitoring of glucose levels in the interstitial fluid as a technique of diabetic monitoring, is considered **experimental, investigational or unproven** because there is insufficient evidence in the peer reviewed medical literature to support its reliability and efficacy. Therefore it is **NOT COVERED**.

CGM using an implantable glucose sensor (e.g., Eversense) is considered experimental, investigational or unproven because there is insufficient evidence in the peer reviewed medical literature to support its reliability and efficacy. Therefore it is **NOT COVERED**

Personal digital assistant-based blood glucose monitoring devices and interface systems (e.g., TheraSense FreeStyle Tracker, Accu-Check Advantage Module, the Dexcom SHARE), and remote glucose monitoring add-on systems (e.g., mySentry) are considered experimental, investigational or unproven because there is insufficient evidence in the peer reviewed medical literature to support its reliability and efficacy. Therefore they are **NOT COVERED.**

The use of long-term continuous glucose monitoring systems for any indication not specifically listed in this policy is considered **experimental, investigational or unproven.** Although the device is FDA approved, there is insufficient evidence in the peer-reviewed published medical literature to establish the effectiveness of this treatment on health outcomes for populations other than those identified in this policy when compared to established treatments or technologies.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven services is outlined in **MP 15 - Experimental Investigational or Unproven Services or Treatment**

Replacement of Continuous Subcutaneous Insulin Infusion pumps for the sole purpose of upgrading or use with a non-covered monitoring device is not considered **medically necessary**.

*Please refer to MP 104 for a description of coverage in regard to Continuous Subcutaneous Insulin Infusion Pump

Medicaid Business Segment:

Any requests for services, that do not meet criteria set in the PARP, may be evaluated on a case by case basis

CODING ASSOCIATED WITH: Continuous Subcutaneous Glucose Monitoring

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

CPT/HCPCS Codes:

S1030 continuous, non-invasive glucose monitoring devices, purchase
0446T Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training
0447T Removal of implantable interstitial glucose sensor from subcutaneous pocket via incision
0448T Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation
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
95250 Glucose monitoring for up to 72 hours by continuous recording and storage of glucose values from interstitial tissue fluid via a subcutaneous sensor (includes hook-up, calibration, patient initiation and training, recording, disconnection, downloading with printout of data)
95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for up to 72 hours; physician interpretation and report
A4238 (Supply allowance for non-implantable adjunctive continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service)
A4253 Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4256 Normal, low and high calibrator solution/chips
A9276 Continuous glucose sensor (No longer valid for Medicare after March 31, 2022)
A9277 Mini-Link Real Time transmitter (No longer valid for Medicare after March 31, 2022)
A9278 Receiver (monitor); external, for use with interstitial continuous glucose monitoring system (No longer valid for Medicare after March 31, 2022)
E0607 Home blood glucose monitor
E2102 (Adjunctive continuous glucose monitor or receiver)
S1031 Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement, and download to monitor
K0553 Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
K0554 Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

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Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Glucose Monitors – Policy Article (A52464) Noridian Healthcare Solutions, LLC

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 05/02

Revised: 6/03 (definition, criteria); 6/04 criteria; 6/05; 6/06; 6/07; 12/07; 9/08(criteria added), 11/11(criteria and exclusions); 8/12 (criteria), 8/16; 6/17 (criteria change to include Type 2); 6/19 (add coverage/exclusion; revise criteria), 5/20 (added Medicaid/Medicare language); 9/20 (add Freestyle Libre 2); 7/22 (revise Medicare criteria)

Reviewed: 9/09, 10/10, 8/13, 8/14, 8/15, 6/18, 9/21

Geisinger Health Plan may refer collectively to health care coverage sponsors Geisinger Health Plan, Geisinger Quality Options, Inc., and Geisinger Indemnity Insurance Company, unless otherwise noted. Geisinger Health Plan is part of Geisinger, an integrated health care delivery and coverage organization.

Coverage for experimental or investigational treatments, services and procedures is specifically excluded under the member's certificate with Geisinger Health Plan. Unproven services outside of an approved clinical trial are also specifically excluded under the member's certificate with Geisinger Health Plan. This policy does not expand coverage to services or items specifically excluded from coverage in the member's certificate with Geisinger Health Plan. Additional information can be found in MP015 Experimental, Investigational or Unproven Services.

Prior authorization and/or pre-certification requirements for services or items may apply. Pre-certification lists may be found in the member's contract specific benefit document. Prior authorization requirements can be found at https://www.geisinger.org/health-plan/providers/ghp-clinical-policies