SmartHealth®

SmartHealth medical coverage policy

Policy: Continuous Glucose Monitor (CGM) devices and external insulin infusion pumps

Review Date: 12/1/2022
Effective Date: 1/1/2018; 2/18/2019

Overview

This document addresses the use of continuous glucose monitoring devices (CGMs, also referred to as continuous *interstitial* glucose monitoring devices), automated insulin delivery systems, and non-implanted insulin pump devices for the management of diabetes mellitus.

Coverage policy

Durable Medical Equipment (DME) including continuous glucose monitors, external insulin pumps and associated diabetic medical supplies are covered by the Plan when medically necessary. Coverage for continuous glucose monitors (CGM), sensors, transmitters and diabetic supplies may be available under the medical benefit or the pharmacy benefit. All requests for new and replacement CGM **devices** require a physician prescription and prior authorization for the device must be obtained. CGM **supplies** (ie; sensors, transmitters & receivers) do not require prior authorization but are subject to the quantity limitations as outlined below in the policy . All of the following conditions of coverage apply:

Continuous Glucose Monitoring System (CGM)

CGM devices are used for the continuous monitoring of interstitial glucose concentrations. These devices have been shown to assist in the management of some individuals with diabetes mellitus.The device provides continuous “real time” readings and data about trends in glucose levels.This may allow people with diabetes to better understand their glucose levels and intervene by eating food or taking insulin to prevent glucose levels from going too high or too low.

Components of CGM device:

- Receiver
- Sensor
- Transmitter

Continuous glucose monitoring (CGM) systems fall into two categories: 1) “professional” (masked) CGM devices that patients wear without being able to see glucose values until their provider downloads and reviews the data retrospectively during an office visit and 2) personal systems affording both real-time observation of continuous data by patients and retrospective review of complete profiles by patients at home, providers in clinic, or remotely.

CGM is proven and medically necessary for managing individuals with diabetes in the following circumstances:

Medically necessary:

***Professional, intermittent, short-term use* of therapeutic** continuous interstitial glucose monitoring device is considered medically necessary for the management of difficult to control insulin treated diabetes mellitus.

- Hypo- or -hyperglycemic episodes unresponsive to adjustments in therapy
- Asymptomatic nocturnal hypoglycemia

Covered for up to 14 days under the medical plan; six separate sessions in any 12 month period. (CPT code 95250, 95251).

Personal long-term use of minimally invasive continuous interstitial glucose monitoring device (HCPCS A4238, E2102, A4239, E2103) including sensors (HCPCS A4238, A9276), transmitters (HCPCS A4238, A9277) and reader/receiver (HCPCS A9278, E2102) as an adjunct to standard care is considered medically necessary for management of type 1 or type 2 diabetes mellitus:

- Freestyle Libre and Freestyle Libre 14 for an individual 18 and older
- Freestyle Libre 2 and Freestyle Libre 3 for an individual age 4 years and older
- Dexcom G6 for individuals age 2 years and older
- OR any other minimally invasive continuous interstitial glucose monitoring device approved by SmartHealth.

T**he following supply quantities apply for minimally invasive continuous glucose monitoring systems:**

• Sensors (HCPCS A4238, A9276)**:**
  • Freestyle Libre 10-day system: three sensors every 30 days
  • Freestyle Libre 14-day system, Freestyle Libre 2 and Freestyle Libre 3: two sensors every 28 days
  • Dexcom G6: three sensors every 30 days

• Transmitters (HCPCS A4238, A9277):
  Dexcom G6: one transmitter every 90 days

• Reader/receiver (HCPCS A9278, E2102):
  Freestyle Libre 10 day and Freestyle Libre 14 day: one reader every 720 days
  Freestyle Libre 2 and Freestyle Libre 3: one reader every 720 days
  Dexcom G6: one receiver every 365 days

Medically necessary for *any* of the following criteria:

A. Individuals greater than or equal to 14 years old with diabetes mellitus (any type) who meet the following criteria:
   1. Inadequate glycemic control, demonstrated by HbA1c measurements between 7.0% and 10.0%, despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **and**
   2. Insulin injections are required multiple times daily or a medically necessary insulin pump is used for maintenance of blood sugar control; **or**

B. Individuals, *regardless of age*, with diabetes mellitus (any type) who meet the following criteria:
   1. Recurring episodes of hypoglycemia; **and**
   2. Inadequate glycemic control despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **and**
   3. Insulin injections are required multiple times daily or a medically necessary insulin pump is used for maintenance of blood sugar control; **or**

C. Individuals with type 1 diabetes who are pregnant, during the course of the pregnancy, who meet the following criteria:
   1. Inadequate glycemic control, including fasting hyperglycemia or with recurring episodes of hypoglycemia in spite of compliance with multiple alterations in self-monitoring and insulin administration regimens to optimize care; **and**

2. Insulin injections are required multiple times daily or a medically necessary insulin pump is used for maintenance of blood sugar control; **and**
3. Multiple blood glucose tests are required daily.

Non therapeutic Continuous Glucose-Monitoring systems

A minimally invasive non-therapeutic continuous glucose monitoring system (CGMS) including sensors (HCPCS A4238, A9276), transmitters (HCPCS A4238, A9277) and reader/receiver (HCPCS A9278, E2102) (e.g., Guardian Sensor 3 (HCPCS A4238, A9276), Guardian® REAL-Time (HCPCS code A4238, A9277, A9278, E2102) used with a fingerstick blood glucose monitor is considered medically necessary for the management of type 1 or type 2 diabetes mellitus when used according to the U.S. Food and Drug Administration (FDA) approved indications and ALL of the following criteria have been met:

WHEN the individual is on EITHER of the following treatment programs:

- Insulin regimen which includes long-acting (basal) insulin and rapid-acting (prandial/mealtime) insulin OR multiple daily injections of U500 insulin
- Continuous subcutaneous external insulin pump

Replacement of a Continuous Glucose Monitoring system and components

The replacement of non-implanted continuous interstitial glucose monitoring devices is considered **medically necessary** when the following criteria have been met:

- The device is out of warranty; **and**
- The device is malfunctioning; **and**
- The device cannot be refurbished.
- There is evidence of an evaluation by a health care provider managing the diabetes within the last 6 months that includes a recommendation supporting continued use of a continuous glucose monitor

Continuous Glucose Monitoring System with an implantable interstitial glucose sensor

Use of implantable interstitial glucose sensors (i.e.; **Eversense CPT codes 0446T, 0447T, G0308, G0309**)) is considered **medically necessary** for individuals when the criteria below have been met:

- The individual is 18 years of age or older; **and**
- The individual meets the medical necessity criteria above for personal long-term use of continuous interstitial glucose monitoring devices (A, B, or C).

The replacement of an implantable interstitial glucose sensor is considered **medically necessary** in accordance with FDA approved indications for use.

Glucose monitoring not covered

Not medically necessary:

Use of continuous interstitial glucose monitoring devices is considered **not medically necessary** for all other indications, including but not limited to when the criteria above have not been met.

Replacement of currently functional and warranted continuous interstitial glucose monitoring devices is considered **not medically necessary** when the replacement of continuous interstitial glucose monitoring devices medically necessary criteria (A, B, and C) above have not been met**.**

Any items considered convenience items are not medically necessary including;

- Additional software required for downloading data to personal computer, phone or tablet to aid in self-management of diabetes unless approved by the SmartHealth plan.
- Devices that include a home blood glucose monitor combined with a cell phone or other device not specifically indicated for diabetes management (blood pressure monitor, cholesterol screening analyzer unless approved by the SmartHealth plan.
- Remote glucose monitoring device (MySentry)
- Hypoglycemic wristband alarm (Diabetes Sentry)

External insulin pumps

Any U. S. Food and Drug Administration (FDA) approved external insulin pump* (HCPCS code E0784) when used according to the FDA approved indication is considered medically necessary for the management of type 1 diabetes.

Any U. S. Food and Drug Administration (FDA) approved external insulin pump* (HCPCS code E0784) when used according the FDA approved indication is considered medically necessary for the management of type 2 diabetes when ALL of the following criteria are met:

External insulin pumps (both disposable and durable) with wireless communication capability are considered **medically necessary** in any of the following groups (A, B, **or** C):

A. Individuals with documented diabetes mellitus (any type) meeting *all* the following criteria (1 through 5):
    1. Completed a comprehensive diabetes education program within the past 2 years; **and**
    2. Follows a program of multiple daily injections of insulin; **and**
    3. Has frequent self-adjustments of insulin doses for the past 6 months; **and**
    4. Requires multiple blood glucose tests daily or is using a continuous glucose monitor; **and**
    5. Has documentation of *any* of the following while on a multiple daily injection regimen:
        a. Glycosylated hemoglobin level (HbA1c) greater than 7.0 percent; **or**
        b. "Brittle" diabetes mellitus with recurrent episodes of diabetic ketoacidosis, hypoglycemia or both, resulting in recurrent and/or prolonged hospitalization; **or**
        c. History of recurring hypoglycemia or severe glycemic excursions; **or**
        d. Wide fluctuations in blood glucose before mealtime; **or**
        e. "Dawn phenomenon" with fasting blood sugars frequently exceeding 200 mg/dl; **or**
        f. Microvascular or macrovascular complications (for example, diabetic retinopathy or cardiovascular disease); **or**
B. Individuals with documented diabetes mellitus (any type) and are pre-conception or currently pregnant, to reduce the incidence of fetal mortality or anomaly; **or**
C. Individuals with diabetes mellitus (any type) successfully using a continuous insulin infusion pump prior to enrollment and requiring multiple blood glucose tests daily during the month prior to enrollment.

Refills for medically necessary disposable external insulin pumps are considered **medically necessary.**

Replacement pumps:

The replacement of external insulin pumps is considered **medically necessary** when the following criteria have been met:

A. The device is out of warranty, **and**
B. The device is malfunctioning, **and**
C. The device cannot be refurbished.

Note: The medical necessity of the replacement of an external insulin pump for pediatric individuals (under 18 years of age) who require a larger insulin reservoir will be considered on a case-by-case basis. The following information is required when submitting requests:

A. Current insulin pump reservoir volume; **and**
B. Current insulin needs; **and**
C. Current insulin change out frequency required to meet individual needs.

Not medically necessary:

The use of external insulin pumps for any indication other than those listed above is considered **not medically necessary.**

Use of a disposable external insulin pump with **no** wireless communication capability (for example, V-Go®, CeQur® Simplicity™) is considered **not medically necessary** under all circumstances.

Replacement of currently functional and warranted external insulin pumps is considered **not medically necessary** when the replacement of external insulin pumps medically necessary **criteria (A, B, and C) above have not been met.**

Coding and billing information (2022)

Continuous Glucose Monitoring System (CGMS)

Considered medically necessary when criteria listed above is met

CPT®* Codes	Description
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	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
95251	Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum 72 hours; analysis, interpretation and report
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

HCPCS Codes	Description
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, one unit = 1 day supply
A9277	Transmitter; external, for use with interstitial continuous glucose monitoring system
A9278	Receiver (monitor); external, for use with interstitial continuous glucose monitoring system
E2102	Adjunctive continuous glucose monitor or receiver
G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training (Code effective 07/01/2022)
G0309	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 180 day implantable sensor, including system activation (Code effective 07/01/2022)
A4239	Supply allowance for therapeutic continuous glucose monitor (CGM), includes all supplies and accessories, 1 month supply = 1 unit of service
E2103	Receiver (monitor), dedicated, for use with therapeutic glucose continuous monitor system

Considered convenience item/not medically necessary and not covered

HCPCS Codes	Description
A9279	Monitoring feature/device, stand-alone or integrated, any type, includes all accessories, components and electronics, not otherwise classified
A9280	Alert or alarm device, not otherwise classified
E1399	Durable medical equipment, miscellaneous

External insulin pumps

Considered medically necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
A4224	Supplies for maintenance of insulin infusion catheter, per week
A4225	Supplies for external insulin infusion pump, syringe type cartridge, sterile, each
A4230	Infusion set for external insulin pump, non needle cannula type
A4231	Infusion set for external insulin pump, needle type
A4232	Syringe with needle for external insulin pump, sterile, 3cc
A9274	External ambulatory insulin delivery system, disposable, each, includes all supplies and accessories
E0784	External ambulatory infusion pump, insulin
E0787	External ambulatory infusion pump, insulin, dosage rate adjustment using therapeutic continuous glucose sensing
S1030	Continuous noninvasive glucose monitoring device , purchase (for physician interpretation of data)
S1031	Continuous noninvasive glucose monitoring device, rental, including sensor, sensor replacement and download to monitor (for physician interpretation of data)
S1034	Artificial pancreas device system (e.g., low glucose suspend (LGS) feature) including continuous glucose monitor, blood glucose device, insulin pump and computer algorithm that communicates with all of the devices
S1035	Sensor; invasive (e.g., subcutaneous), disposable, for use with artificial pancreas device system
S1036	Transmitter; external, for use with artificial pancreas device system
S1037	Receiver (monitor); external, for use with artificial pancreas device system
S9145	Insulin pump initiation, instruction in initial use of pump (pump not included)

Diabetic supplies

Considered medically necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
A4206	Syringe with needle, sterile, 1 cc or less, each
A4208	Syringe with needle, sterile, 3cc, each
A4211	Supplies for self-administered injections

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A4215	Needle, sterile, any size, each
A4245	Alcohol wipes, per box
A4247	Betadine or iodine swabs/wipes, per box
A4250	Urine test or reagent strips or tablets (100 tablets or strips)
A4252	Blood ketone test or reagent strip, each
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
S5560	Insulin delivery device, reusable pen; 1.5 ml size
S5561	Insulin delivery device, reusable pen; 3 ml size
S5570	Insulin delivery device, disposable pen (including insulin); 1.5 ml size
S5571	Insulin delivery device, disposable pen (including insulin); 3 ml size
S8490	Insulin syringes (100 syringes, any size)

Considered experimental/investigational/unproven when used to report a home glycated serum protein (GSP) monitor:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

Considered not medically necessary/convenience item when used to report home glycated hemoglobin (A1C) monitors, hypoglycemic wristband alarm (e.g., sleep sentry), laser lancet and/or insulin infusers (e.g., i-port®):

HCPCS Codes	Description
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
E0620	Skin piercing device for collection of capillary blood, laser, each
E1399	Durable medical equipment, miscellaneous

12/01/2022- Continuous Glucose Monitoring devices and external insulin infusion devices policies combined into one policy. Coverage and CPT codes updated to reflect current standard of care.

12/01/2022- Policy approved by Ascension Insurance CMO and SmartHealth plan sponsor

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References:

Cigna Medical Coverage Policy
Diabetic Equipment and Supplies

Anthem BCBS Coverage Policy
Continuous Glucose Monitoring Devices and External Insulin Infusion Pumps

United Healthcare Commercial Medical Policy
Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes

Aetna Clinical Policy Bulletin
Diabetes tests, programs and supplies


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