RB. 017.C Continuous Glucose Monitors (CGM's)

Original Implementation Date: 08/29/2020
Version [C] Date: 12/9/2022
Last Reviewed Date: 2/8/2023

PRODUCT VARIATIONS

This policy applies to all Jefferson Health Plans (JHP) lines of business unless noted below.

POLICY STATEMENT

THEREPEUTIC CONTINUOUS GLUCOSE MONITORING SYSTEMS

The **Dexcom G6** Glucose Monitoring System (A4239, E2103) will be considered for reimbursement for individuals aged 2-19 when the below criteria are met:

- The member has established diagnosis of Diabetes Type I or Type 2.
- Medical necessity criteria are met (American Diabetic Association - Standards of medical care in diabetes 2022. Centers for Medicare & Medicaid Services 2022 or NCD/LCD; InterQual®).
- The member is treated with insulin multiple (three or more) daily injections or continuous subcutaneous insulin infusion (CSII) pump; and,
- The member's insulin treatment regimen requires frequent adjustments based on SBGM (self-blood glucose monitoring) or CGM testing results; and,
- Within six (6) months prior to ordering the CGM, the treating practitioner has an in person visit with the member to evaluate their diabetes control and determine that criteria above are met.

The **FreeStyle Libre Flash** Glucose Monitoring System (A4239, E2103) will be considered for reimbursement for individuals 18 years of age or older when the following criteria are met:

- The member has established diagnosis of Diabetes Type I or Type II

- Medical necessity criteria are met (American Diabetic Association. Standards of medical care in diabetes 2022. Centers for Medicare & Medicaid Services 2022 or NCD/LCD; InterQual®.

- The member is treated with insulin multiple (three or more) daily injections or continuous subcutaneous insulin infusion (CSII) pump; and,

- The member's insulin treatment regimen requires frequent adjustments based on SBGM (self-blood glucose monitoring) or CGM testing results; and,

- Within six (6) months prior to ordering the CGM, the treating practitioner has an in person visit with the patient to evaluate their diabetes control and determine that criteria above are met.

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.

**** Codes A9276, A9277, A9278 do not apply to Medicare***

When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. Supplies (codes A4238 & A4239) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the beneficiary meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump (Centers for Medicare & Medicaid Services 2022 or NCD/LCD; InterQual®).

Continuous Glucose Monitoring System with an Implantable Interstitial Glucose Sensor

A continuous glucose monitoring system with an implantable interstitial glucose sensor (i.e., Eversense®) (CPT® codes 0446T, 0447T, 0448T, G0308, G0309) is considered medically necessary for the management of type 1 or type 2 diabetes mellitus for an individual age 18 years or older who 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/RENEWAL

Replacement or renewal of an existing continuous glucose monitoring system, or components for the management of diabetes type I or II requires information of both:

- Documentation confirming that the current continuous glucose monitor/component is malfunctioning, no longer under warranty and cannot be repaired.

- Documentation, showing a recent (within past 6 months) evaluation by a healthcare provider managing member's diabetes with supporting data from the record showing how the member benefits from the use of this device.

Prior authorization is required for rentals and DME over $500.

For determination of Medical Necessity, the reviewer should use current accepted standards of care (American Diabetic Association. Standards of medical care in diabetes 2022. Centers for Medicare & Medicaid Services 2022) or NCD/LCD; InterQual®.

Continuous Glucose Monitors (CGM) are a covered service under the DME (Durable Medical Equipment) benefit according to the individual's eligibility and JHP benefit plan.

The **FreeStyle Libre Flash** Glucose Monitoring System (A4239 & E2103) is available through the Pharmacy benefit and does not require prior authorization.

Types of CGM's:

Therapeutic (non-adjunctive)

- These CGMs currently include Dexcom 5 and Dexcom 6, and Freestyle Libre 14 day.

- These CGMs use HCPCS codes (A4239 & E2103).

- Dexcom G5 requires fingerstick calibration once per 12 hours whereas the G6 and Libre 14 day do not.

- Can be used for therapeutic decision making.
- Dexcom G6 can interface with some insulin pumps directly.
- Freestyle Libre is an intermittent (or flash) device which does not have alarms or continuous communication (sensor must be scanned).
- The Receiver, E3103, has a reasonable useful lifetime of 3 years.

Non-Therapeutic (adjunctive)

- These CGMs currently include Medtronic Guardian® Sensor 3, Guardian® REAL-Time and Sensonics Eversense
- These GMS use HCPCS codes (A4238, A9276, A9277, A9278, E2102, 0446T, 0447T, 0448T)
- This type of CGM is also called adjunctive and require finger stick glucose testing for calibration (which may mean additional costs for supplies).
- The supplies may be billed monthly using a daily rate. This means that the monthly allowance for A9276 is 30 units, 180 units for 6 months.
    - Transmitters (A9277) are allowed once every 3 months (1 unit per 3 months).
- The receiver, A9278, has a reasonable useful lifetime of 3 years.

INTERQUAL®CATEGORIES

InterQual® will ask which category of CGM is being requested from the following:

- CGM to be used adjunctively with a self-monitoring blood glucose (SMBG) device.
- Non-adjunctive CGM device with daily SMBG device for daily calibration [Dexcom G5].
- Non-adjunctive, factory calibrated, integrated CGM [Dexcom G6].
- Flash monitor (sensor, glucose, invasive, non-adjunctive, factory-calibrated, user
    - initiated [Freestyle Libre 14 day].

POLICY GUIDELINES

N/A

CODING

Note: The Current Procedural Terminology (CPT®), Healthcare Common Procedure Coding System (HCPCS), and the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10) codes that may be listed in this policy are for reference purposes only. ***Listing of a code in this policy does not imply that the service is covered and is not a guarantee of payment.*** *Other policies and coverage guidelines may apply. When reporting services, providers/facilities should code to the highest level of specificity using the code that was in effect on the date the service was rendered. This list may not be all inclusive.*

CPT Code	Description
N/A	

THERAPEUTIC (NON-ADJUNCTIVE) CONTINUOUS GLUCOSE MONITORS

HCPCS Codes	Description
A4239 *	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver

*Code A4239 includes ALL ITEMS necessary for use of the device and includes, but not limited to CGM sensor, CGM transmitter, home Blood glucose monitor and all related Blood glucose monitor supplies, and batteries.

NON-THERAPEUTIC (ADJUNCTIVE) CONTINUOUS GLUCOSE MONITORS

Code	Description
A4238	Supply allowance for adjunctive continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102	Adjunctive continuous glucose monitor or receiver
A9276	Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial continuous glucose monitoring system, 1 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
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
G0308	Creation of subcutaneous pocket with insertion of 180 day implantable interstitial glucose sensor, including system activation and patient training
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

ICD-10 Codes	Description
N/A	

BENEFIT APPLICATION

This Reimbursement Policy does not constitute a description of benefits. Rather, this assists in the administration of the member's benefits which may vary by line of business. Applicable benefit documents govern which services/items are eligible for coverage, subject to benefit limits, or excluded completely from coverage.

DESCRIPTION OF SERVICES

OVERVIEW

- Maintaining glucose levels close to normal reduces the chance of developing microvascular complications of diabetes.

- Consistent monitoring of glucose levels helps with condition management.
- Monitoring glucose levels can be accomplished through:

- Self-monitoring blood glucose (SMBG): measures a small amount of blood (usually from the fingertip) using a glucose meter 3 to 4 times per day. SMBG looks at specific glucose values at specific points in time, generating a gross pattern of variability.

- Continuous glucose monitoring (CGM): measures glucose levels in the interstitial fluid through the use of a sensor placed under the skin. A transmitter sends information about glucose levels to a wireless monitor attached externally. These devices display glucose levels at either 1- or 5-minute intervals with the option to set alarms alerting the individual to abnormal glucose levels.

  Greater amounts of data collection may provide more insight regarding glucose patterns.

DEFINITIONS

What is the difference between a therapeutic and non-therapeutic Continuous Glucose Monitor (CGM)?

1. A "therapeutic" CGM is a system approved by the FDA as a replacement for home blood glucose monitors. It performs the medically necessary function of the home glucose monitor to make diabetes treatment decisions.

2. A "non-therapeutic" CGM device is used as an adjunct to home blood glucose monitor testing. It is not a replacement for home blood glucose monitors. It does not perform a medically necessary function and is not used to make diabetes treatment decisions. Any CGM system that does not have the FDA designation would be considered a "non-therapeutic" CGM.

DISCLAIMER

Approval or denial of payment does not constitute medical advice and is neither intended to guide nor influence medical decision making.

Policy Bulletins are developed by Jefferson Health Plans (JHP) to assist in administering plan benefits and constitute neither offers of coverage nor medical advice.

This Policy Bulletin may be updated and therefore is subject to change.

POLICY HISTORY

This section provides a high-level summary of changes to the policy since the previous version.

Summary	Version	Version Date
2023 HCPCS code update. The following codes were added to the policy: A4239 & E2103. The following codes were removed from the policy: K0553 & K0554.	C	12/9/2022
Coverage criteria was added for non-therapeutic continuous glucose monitoring system (CGMS). The following codes were added to the policy: A4238, E2102, 0446T, 0447T, 0448T.	C	12/9/2022
Policy language revised for clarity.	B	3/19/2021
This is a new policy.	A	8/29/2020

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