Continuous Glucose Monitoring Systems (CGMS)
Policy Number: C17737-A

CRITERIA EFFECTIVE DATES:

<table>
<thead>
<tr>
<th>ORIGINAL EFFECTIVE DATE</th>
<th>LAST REVIEWED DATE</th>
<th>NEXT REVIEW DUE BY OR BEFORE</th>
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<tr>
<td>11/20/2008</td>
<td>3/17/2022</td>
<td>4/26/2022</td>
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J CODE | TYPE OF CRITERIA | LAST P&T APPROVAL/VERSION
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A9276-Sensor; invasive, disposable, for use with interstitial continuous glucose monitoring system, 1 unit = 1-day supply | RxPA | Q2 2021 20210428C17737-A
A9277-Transmitter; external, for use with interstitial continuous glucose monitoring system | | |
A9278-Receiver (monitor); external, for use with interstitial continuous glucose monitoring system | | |

PRODUCTS AFFECTED:
Dexcom G4, Guardian REAL-Time, Dexcom G4, FreeStyle Libre 10-day Reader DEVI, Dexcom G6 Receiver, FreeStyle Libre 14 Day Reader, Dexcom G5

***For single-use, disposable and nonprogrammable/mechanical (non-electric) insulin infusion pumps (e.g., V-Go™ Disposable Insulin Delivery Device, OmniPod)- REFER TO DISPOSABLE INSULIN DELIVERY DEVICE CRITERIA***

*** FOR MEDTRONI MINIMED MODELS INTENDED TO BE USED IN COMBINATION WITH INSULIN PUMPS- REFER TO HEALTHCARE SERVICES TO REVIEW FOR INSULIN PUMP COVERAGE***

Glucose Monitoring Test Supplies

ROUTE OF ADMINISTRATION:
Subcutaneously

PLACE OF SERVICE:
Retail Pharmacy
The recommendation is that medications in this policy will be for pharmacy benefit coverage and patient self-administered

AVAILABLE DOSAGE FORMS:
*Continuous Blood Glucose Monitor System/Components Kit***
Guardian REAL-Time Starter KIT, Guardian REAL-Time System Ped KIT, Guardian RT System KIT, Paradigm REAL-Time Starter KIT

*Continuous Blood Glucose System Receiver***
Dexcom G4 Plat Ped Rcv/Share DEVI, Guardian REAL-Time Replace Ped DEVI, Dexcom G4
Prior Authorization Criteria

Platinum Rcv/Share, Dexcom Receiver Kit, FreeStyle Libre 10-day Reader DEVI, Dexcom G6 Receiver, FreeStyle Libre 14 Day Reader, Dexcom G5 Mobile Receiver

*Continuous Blood Glucose System Sensor***


*Continuous Blood Glucose System Transmitter***

Guardian Link 3 Transmitter, Guardian Connect Transmitter, Dexcom G5 Mobile Transmitter, Dexcom G6 Transmitter, Guardian Link 3 Transmitter, Dexcom G4 Platinum Transmitter Eversense Smart Transmitter, Guardian Link 3 Transmitter, Guardian Connect Transmitter Guardian Transmitter

**FDA-APPROVED USES:**

Indicated for detecting trends and tracking patterns and glucose level excursions above or below the desired range, facilitating therapy adjustments in persons with diabetes

In people with type 2 diabetes not using insulin, routine glucose monitoring may be of limited additional clinical benefit.

**COMPENDIAL APPROVED OFF-LABEL USES:**

None

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**COVERAGE CRITERIA: INITIAL AUTHORIZATION**

**DIAGNOSIS:**

INSULIN DEPENDENT DIABETES

**REQUIRED MEDICAL INFORMATION:**

**A. INSULIN DEPENDENT DIABETES- ADULTS (≥18 YEARS OF AGE):**

1. (a) Documented diagnosis of type 1 or 2 diabetes
   OR
   (b) Documentation member is pregnant receiving insulin therapy
   **AND**

2. Prescriber attests to patient scheduled to or historical completion (within the last 12 months) of a comprehensive diabetic education program, training and support for the CGM device **AND** patient or caregiver has the ability to perform self-monitoring of blood glucose in order to calibrate the monitor if needed and/or verify readings if discordant from their symptoms.
   **AND**

3. Prescriber attests member and/or caregiver has been counseled on potential drugs/substances that can falsely raise or lower CGM glucose levels such as APAP, ASA, vitamin C etc.
   **AND**

4. Documentation of frequency of glucose self-testing at least 4 times per day during the previous month [DOCUMENTATION REQUIRED- medical record, patient testing logs, etc.]
   **AND**

5. Documentation that patient is compliant with insulin injections that are required 3 or more times per day or an insulin pump [DOCUMENTATION OF MONITORING LOGS OR CLAIMS HISTORY]
   **AND**

6. Documentation that insulin dose is adjusted based on self-testing results, **AND:** (a)
Prior Authorization Criteria

Inadequate glycemic control despite compliance with frequent self-testing; and (b) i. Fasting hyperglycemia (greater than 150 mg/dl) or ii. Recurring episodes of severe hypoglycemia (less than 50 mg/dl)
AND
7. Documentation of ANY of the following: (a) Persistent, recurrent unexplained severe hypoglycemic events OR (b) Hypoglycemia unawareness OR (c) Episodes of ketoacidosis OR (d) Hospitalizations for uncontrolled glucose levels OR (e) i. Frequent nocturnal hypoglycemia despite appropriate modifications in insulin therapy AND ii. HbA1c above 7% and have demonstrated compliance with an intensive insulin regimen and blood glucose monitoring 4 or more times a day
AND
8. FOR NON-PREFERRED OR NON-FORMULARY PRODUCTS ONLY: One of the following:
   (1) Patient has a physical or mental limitation that makes utilization of Dexcom G5 and Dexcom G6 unsafe, inaccurate or otherwise not feasible (e.g. manual dexterity; document limitation) OR
   (2) Patient has a physical or mental limitation that makes utilization of Freestyle Libre unsafe, inaccurate or otherwise not feasible (e.g. manual dexterity; document limitation) OR
   (3) Patient already has a NON-FORMULARY/NON-PREFERRED MONITORING SYSTEM and prior authorization request is for continuation of sensor and/or transmitter
B. INSULIN DEPENDENT CHILDREN (<18 YEARS OF AGE):
   1. Documented diagnosis of type 1 diabetes
   AND
   2. Prescriber attests to patient and/or caregiver are scheduled to (within 30 days) or historical completion (within the last 12 months) of a comprehensive diabetic education program, training and support for the CGM device AND patient or caregiver has the ability to perform self-monitoring of blood glucose in order to calibrate the monitor if needed and/or verify readings if discordant from their symptoms
   AND
   3. Documentation member and/or caregiver has been counseled on potential drugs/substances that can falsely raise or lower CGM glucose levels such as APAP, ASA, vitamin C etc.
   AND
   4. Documentation prescriber has counseled the patient and/or caregiver on the importance of continuous daily use for optimal outcomes
   AND
   5. FOR NON-PREFERRED OR NON-FORMULARY PRODUCTS ONLY: One of the following: Patient has a physical or mental limitation that makes utilization of Dexcom G5 and Dexcom G6 unsafe, inaccurate or otherwise not feasible (e.g. manual dexterity; document limitation) OR
   (2) Patient has a physical or mental limitation that makes utilization of Freestyle Libre unsafe, inaccurate or otherwise not feasible (e.g. manual dexterity; document limitation) OR
   (3) Patient already has a NON-FORMULARY/NON-PREFERRED MONITORING SYSTEM and prior authorization request is for continuation of sensor and/or transmitter
DURATION OF APPROVAL:
Long Term CGMS: ALL PARTS- 12 months (for replacement within the 12 months, the device is malfunctioning and is out of warranty; Continuation of therapy- all parts: 12 months
*** FOR FREESTYLE LIBRE APPROvals- PLEASE ALSO ENTER AN AUTHORIZATION FOR FREESTYLE NEO TEST STRIPS [NDC- 57599157904(50ct) 57599157701(25ct)- up to 200 test strips/month] FOR PATIENT TO USE IF NEEDED DURING “WARM-UP” PERIOD FOR SENSOR CHANGES***
Prior Authorization Criteria

QUANTITY:

<table>
<thead>
<tr>
<th>Sensors</th>
<th>Quantity Limit per 30 days</th>
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<tbody>
<tr>
<td>Freestyle Libre 10day</td>
<td>3 per 30 days OR</td>
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<tr>
<td>Freestyle Libre 14 days</td>
<td>2 per 28 days OR</td>
</tr>
<tr>
<td>Dexcom G5 (7 days)</td>
<td>4 per 28 days OR</td>
</tr>
<tr>
<td>Dexcom G6 (10 days)</td>
<td>3 per 30 days OR</td>
</tr>
<tr>
<td>Dexcom G4 (7 days)</td>
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<tr>
<td>Medtronic Guardian Connect (7 days)</td>
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<table>
<thead>
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<tbody>
<tr>
<td>Dexcom G5</td>
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</tr>
<tr>
<td>Dexcom G6</td>
<td>1 transmitter per 90 days OR</td>
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<tr>
<td>Dexcom G4</td>
<td>1 transmitter per 180 days</td>
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<tr>
<td>Medtronic Guardian Connect</td>
<td>1 transmitter per 365 days</td>
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<table>
<thead>
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<th>Receiver</th>
<th>Quantity Limit per 365 Days</th>
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<tbody>
<tr>
<td>Dexcom G5 Receiver (Dexcom Receiver Kit)</td>
<td>1 receiver</td>
</tr>
<tr>
<td>FreeStyle Libre Flash Glucose Monitoring System</td>
<td>1 receiver</td>
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PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified endocrinologist or maternal fetal medicine specialist (for gestational diabetes patients)

AGE RESTRICTIONS:
2 years of age and older

CONTINUATION OF THERAPY:
A. ALL INDICATIONS:
1. Documentation of objective evidence (decrease Hgb A1C, increased adherence, decreased hypoglycemic episodes, etc.) of improvement in control of diabetes specific to baseline status of disease for individual patients
   AND
2. For replacement of the device (RECEIVER): documentation that the receiver is malfunctioning and out of warranty.
   AND
3. There is objective documented evidence from the treating endocrinologist of compliance to CGMS defined as at least 80% use rate of device (must be based on log data of the device)

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION: Implantable glucose sensors, such as Eversense, for continuous glucose monitoring are considered experimental, investigational and unproven (E/I/U) based on insufficient evidence in the peer reviewed medical literature.

OTHER SPECIAL CONSIDERATIONS:
None

BACKGROUND:
Continuous glucose monitoring systems (CGMS) (also known as Real-Time or interstitial) are implantable or noninvasive devices that measure glucose levels in interstitial fluid. A sensor transmits results to a small recording device that can be worn on clothing, placed in a purse or kept within a short distance of the person. The sensor will display and record blood glucose levels at short intervals, allowing observation of these levels. An alarm display can be set to notify a patient of high or low glucose levels. The information can be obtained in real time or retrospectively to guide a physician in therapy adjustments, with an overall goal of improving glycemic control. The glucose values obtained from these devices are not intended to replace standard finger stick self-monitoring of blood glucose (SMBG) but are used as an adjunct technique to supply additional information on glucose trends that are not available from self-monitoring.

There are three types of CGMS:

**Short Term**: Short-term CGM may be used by the treating physicians as a one-time evaluation tool for up to 14 days utilizing the ability of glucose sensors to measure and record glucose levels in interstitial fluid and produce data that shows trends in glucose measurements. The stored information is retrieved and evaluated by the physician for widely varying glucose readings that may be missed by intermittent measurements. The information may be used by the physician to alter the current testing regimen and, ultimately obtain tighter control of glucose levels.

There is a large body of evidence in the published peer-reviewed literature that supports short term intermittent CGMS when used in conjunction with SMBG to aid in the management of adults with type 1 diabetes who are difficult to control and not achieving treatment goals. Many study sizes were large (up to 500), and follow-up was between 1-18 months. Studies included systematic reviews, meta-analysis and randomized controlled trials that reported the use of CGM was associated with a reduction in glycosylated hemoglobin level, as a measure of glycemic control, or stabilization of blood glucose levels.

**Long Term**: Long-term CGM (> 14 days) are for personal use at home and measure glucose in the interstitial fluid using a wire-like sensor that is implanted subcutaneously into the abdomen. The sensor tip reacts with the glucose in the interstitial fluid to generate an electrical current that is converted to a glucose reading. The monitor displays the reading, the direction of the glucose trend, and sounds an alarm when high-or low-glucose values are detected. Monitoring is used by the patient to closely monitor their glucose levels and better manage their diabetes. For most devices, glucose measurements provided during continuous monitoring are not intended to replace standard self-monitoring of blood glucose (SMBG) obtained using fingerstick blood samples but can alert individuals of the need to perform SMBG.

Evidence also supports the safety and efficacy of long-term CGMS with or without insulin pump therapy in the management of adults with type 1 diabetes with uncontrolled blood glucose levels despite appropriate management and adherence to a prescribed diabetic regimen. Study sizes were large (n=60 to >500), and follow-up was between 1-18 months. Cochrane, systematic reviews, meta-analysis, and randomized controlled trials reported reductions in A1c levels that were maintained throughout the studies, as well as fewer hypo- and hyperglycemic events.

**Long Term Interstitial Integrated with Insulin Pump (also known as “open loop” system)**. Some CGMS can integrate with an external insulin pump. The sensor can transmit glucose data to an external insulin pump. The pump can also calculate recommended insulin doses, which the patient can accept or modify. The insulin is delivered using an infusion set (a flexible delivery cannula with a small needle on the end) through a pump about the size of a pager which can be worn on a belt. The pump displays the reading, the direction of the glucose trend, and sounds an alarm when high-or low-glucose values are detected.

**CGMS use in Pregnancy, Children and Adolescents and type 2 Diabetes**

The evidence is sufficient and supports the safety and efficacy of CGMS in women with gestational diabetes, and in children and adolescents with type 1 diabetes. In the pediatric population, studies found that constant or nearly constant use of CGM for 3 to 12 months was associated with
statistically significant absolute reductions of 0.2% to 1.0% in mean HbA1c (e.g., an HbA1c level decreasing from 8.0% to 7.0% represents an absolute decrease of 1.0%). RCT’s, systematic reviews and meta-analysis reported that CGMS improves glycemic control and reductions in A1c levels. In pregnancy RCT’s found that use of CGM was associated with statistically significant improvements in mean HbA1c, mean infant birth weight, and risk of macrosomia. In type 2 diabetes a large trial (n = 600) treated with oral agents were randomly assigned to SMBG or non-SMBG groups. After 27 weeks, A1C decreased in both groups but, there was a significantly greater reduction in A1C in the SMBG group (between-group difference 0.25 percent). The evidence is insufficient to support CGMS in adults with type 2 diabetes.

**Implantable Sensor CGMS**
The overall body of evidence is insufficient to support the safety and efficacy of the Implantable Sensor CGMS such as the Eversense in adults with type 1 or type 2 diabetes. Studies evaluating the clinical validity and clinical utility of the Eversense CGM system are small in size and low in quality due to inconsistencies and variability in assessments of clinical validity and insufficient evidence to evaluate the clinical utility. The evidence suggests moderate accuracy of the Eversense CGM, however the body of evidence is limited by an evidence base of fair to poor-quality studies, small number of patients, limited data assessing the accuracy of the CGM across different glucose parameters, and inconsistencies between studies. No studies compared the clinical utility of the Eversense CGM with SMBG. Limitations of individual studies include small sample size, lack of long-term data, limited reporting of statistical analyses, lack of power analysis, manufacturer funding, author conflicts of interest, and a lack of reporting of patient recruitment methods.

**APPENDIX:**

**REFERENCES:**


