Original Effective Date: 11/20/2008
Current Effective Date: 05/31/2024
Last P&T Approval/Version: 04/24/2024
Next Review Due By: 04/2025
Policy Number: C17737-A

Continuous Glucose Monitoring Systems (CGMS)

PRODUCTS AFFECTED

Dexcom G6, Dexcom G7, FreeStyle Libre 14 Day, Freestyle Libre 2, Freestyle Libre 3, Guardian Connect

***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 C17724-A ***

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

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Insulin dependent diabetes

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a

mandatory generic and that generic drugs will be dispensed whenever available.

A. INSULIN DEPENDENT DIABETES:

1. (a) Documented diagnosis of insulin dependent type 1 or 2 diabetes
   OR
   (b) Documentation member is pregnant receiving insulin therapy
   AND
2. Prescriber attests that member/caregiver is scheduled to (within 30 days) or has historical completion (within the last 12 months) of training and support for the CGM device AND member/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 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) Frequent nocturnal hypoglycemia despite appropriate modifications in insulin therapy
   OR
   (f) Member is compliant with insulin injections that are required 1 or more times per day or an insulin pump
   OR
   (g) Member has a diagnosis of gestational diabetes

   AND
5. FOR NON-PREFERRED OR NON-FORMULARY PRODUCTS ONLY: One of the following:
   (a) Member has a physical or mental limitation that makes utilization of Dexcom G6 and Dexcom G7 unsafe, inaccurate or otherwise not feasible (e.g., manual dexterity, document limitation)
   OR
   (b) Member 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
   (c) Member 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 insulin dependent type 1 or type 2 diabetes
   AND
2. Prescriber attests that member and/or caregiver are scheduled to (within 30 days) or have historical completion (within the last 12 months) of a comprehensive diabetic education program, training and support for the CGM device AND the member 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 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:
   (a) Member has a physical or mental limitation that makes utilization of Dexcom G6 and Dexcom G7 unsafe, inaccurate or otherwise not feasible (e.g., manual dexterity, document limitation)
   OR
   (b) Member 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
   (c) Member already has a NON-FORMULARY/NON-PREFERRED monitoring system and prior authorization request is for continuation of sensor and/or transmitter

CONTINUATION OF THERAPY:

A. ALL INDICATIONS (TYPE 1 OR 2 DIABETES MELLITUS ONLY):

1. Documentation of objective evidence (e.g., decrease Hgb A1C, increased adherence, decreased hypoglycemic episodes, etc.) of improvement in control of diabetes specific to baseline status of disease for individual member
   AND
2. For replacement of the device (RECEIVER): Documentation that the receiver is malfunctioning and out of warranty.
   AND
3. Documentation of compliance to CGM regimen defined as at least 80% use rate of device (must be based on log data of the device)

DURATION OF APPROVAL:

Gestational Diabetes: Initial Authorization: All parts - Estimated date of delivery plus up to 3 months to determine post-delivery insulin and monitoring needs; Continuation of therapy: N/A
All other indications: Initial authorization: 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 member to use if needed during “warm-up” period for sensor changes

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an endocrinologist or nurse practitioner/physician assistant working with an endocrinologist. Other prescribers, e.g., PCPs, must consult with an endocrinologist or nurse practitioner/physician assistant working with an endocrinologist.
FOR GESTATIONAL DIABETES: Prescribed by or in consultation with an obstetrician-gynecologist or fetal medicine specialist, or endocrinologist or nurse practitioner/physician assistant working with an endocrinologist.
MOLINA REVIEWER NOTE: Special consideration should be given if the requesting provider attests a specialist is unavailable in member’s vicinity, if specialist appointments are not available timely, if CDE is available through MCO or PCP program, and/or the provider requesting CGM is actively managing the member’s diabetes and insulin regimen.
[If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

Dexcom G6 & G7: 2 years of age and older
Freestyle Libre 2 & 3: 4 years of age and older
Freestyle Libre 14 day: 18 years of age and older
Guardian Connect: 14 years of age and older

QUANTITY:

Sensors	**Quantity Limit per 30 days**
Freestyle Libre 14 days	2 per 28 days
Freestyle Libre 2	2 per 28 days
Freestyle Libre 3	2 per 28 days
Dexcom G6 (10 days)	3 per 30 days
Dexcom G7 (10 days)	3 per 30 days
Medtronic Guardian Connect (7 days)	5 per 35 days
Transmitters	**Quantity Limit per 90 days**
Dexcom G6	1 transmitter per 90 days
Medtronic Guardian Connect	1 transmitter per 365 days
Receiver	**Quantity Limit per 365 Days**
Dexcom G6 Receiver	1 receiver
Dexcom G7 Receiver	1 receiver
Freestyle Libre Flash Glucose Monitoring System	1 receiver
Freestyle Libre 2 Reader	1 receiver

Note: Freestyle Libre 3 and Guardian Connect do not require receivers. Member's smart device acts as receiver.
Quantity limits over time apply across models/generations/systems. Change in model/generation/system does not constitute need for quantity override within the time frames specified.

PLACE OF ADMINISTRATION:
The recommendation is that testing supplies in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous

DRUG CLASS:
Glucose Monitoring Test Supplies

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-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

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 maybe 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 1diabetes 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.

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

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
A9276	Sensor; invasive, 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
A4238	Supply allowance for adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
A4239	Supply allowance for non-adjunctive, non-implanted continuous glucose monitor (cgm), includes all supplies and accessories, 1 month supply = 1 unit of service
E2102	Adjunctive, non-implanted continuous glucose monitor or receiver
E2103	Non-adjunctive, non-implanted continuous glucose monitor or receiver

Note: The term “therapeutic” may be used interchangeably with the term “non-adjunctive.” Likewise, the term “non-therapeutic” may be used interchangeably with the term “adjunctive.”

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**
Guardian REAL-Time Replace Ped DEVI, Dexcom Receiver Kit, Dexcom G6 Receiver, FreeStyle Libre 14 Day Reader,

Continuous Blood Glucose System Sensor**
Enlite Glucose Sensor, Sof-Sensor, MiniMed Guardian Sensor 3, Dexcom G6 Sensor, FreeStyle Libre 14 Day Sensor, Guardian Sensor (3), Eversense Sensor/Holder

Continuous Blood Glucose System Transmitter**
Guardian Link 3 Transmitter, Guardian Connect Transmitter, Dexcom G6 Transmitter, Eversense Smart Transmitter, Guardian Transmitter

REFERENCES

1. American Diabetes Association (ADA): American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes 2022. Diabetes Care 2022; 45:S97-S112.
2. Kudva YC, Ahmann AJ, Bergenstal RM, et al. Approach to Using Trend Arrows in the FreeStyle Libre Flash Glucose Monitoring Systems in Adults. J Endocr Soc 2018; 2:1320.
3. Bailey TS, et al. American Association of Clinical Endocrinologists and American College of Endocrinology (AACE/ACE) Outpatient Glucose Monitoring Consensus Statement. Endocrine Pract 2016 Feb;22(2):231-260.
4. Ajjan R, Slattery D, Wright E. Continuous glucose monitoring: A brief review for primary care practitioners. Adv Ther. 2019.1:1-19. doi.org/10.1007/s12325-019-0870-x.
5. Danne T, Nimri R, Battelino T, et al. International consensus on use of continuous glucose monitoring. Diabetes Care. 2017;40:1631–40
6. Newman SP et al. A randomised controlled trial to compare minimally invasive glucose monitoring devices with conventional monitoring in the management of insulin-treated diabetes mellitus (MITRE). Health Technol Assess. 2009 May;13(28):iii-iv, ix-xi, 1-194.
7. Wojciechowski P et al. Efficacy and safety comparison of continuous glucose monitoring and self-monitoring of blood glucose in type 1 diabetes: systematic review and meta-analysis. Pol Arch Med Wewn. 2011 Oct;121(10):333-43. Accessed at: http://pamw.pl/sites/default/files/pamw_2011-10_BZ-Malecki_0.pdf
8. Blevins TC et al. AACE Consensus Statement. Statement by the American Association of Clinical Endocrinologists Consensus Panel on Continuous Glucose Monitoring. Endocrine Practice 2010.16:440-56.Accessed at: http://www.aace.com/files/ContinuousGlucoseMonitoring.pdf
9. Pickup JC, Freeman SC, Sutton AJ. Glycaemic control in type 1 diabetes during real-time continuous glucose monitoring compared to self-monitoring of blood glucose: meta-analysis of randomised controlled trials using individual patient data. BMJ 2011;343:d3805. Accessed at: http://www.bmj.com/content/343/bmj.d3805.full
10. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for

Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017; 317(4):379-387.
11. Beck RW, Riddlesworth T, Ruedy K, et al.; DIAMOND Study Group. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017 Jan 24;317(4):371-378.
12. Riddlesworth T, Price D, Cohen N, Beck RW. Hypoglycemic Event Frequency and the Effect of Continuous Glucose Monitoring in Adults with Type 1 Diabetes Using Multiple Daily Insulin Injections. Diabetes Ther. 2017 Aug;8(4):947-951. doi: 10.1007/s13300-017-0281-4. Epub 2017 Jun 14.
13. Faccioli S, Del Favero S, Visentin R et al. Accuracy of a CGM sensor in pediatric subjects with type 1 diabetes. Comparison of three insertion sites: Arm, abdomen, and gluteus. J Diabetes Sci Technol. 2017;May 01
14. Ruedy KJ(1), Parkin CG(2), Riddlesworth TD et al. Continuous Glucose Monitoring in Older Adults With Type 1 and Type 2 Diabetes Using Multiple Daily Injections of Insulin: Results From the DIAMOND Trial. J Diabetes Sci Technol. 2017 Apr 1:1932296817704445.
15. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2023. Diabetes Care 2023; 46 (Suppl. 1): S140-S157. https://doi.org/10.2337/dc23-S009
16. Pharmacologic Approaches to Glycemic Treatment: Standards of Care in Diabetes – 2024. Diabetes Care 2024; 47 (Suppl. 1): S158-S178. https://doi.org/10.2337/dc24-S009
17. Diabetes Technology: Standards of Care in Diabetes – 2024. Diabetes Care 2024; 47 (Suppl. 1): S126-S144. https://doi.org/10.2337/dc24-S0097

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: References	Q2 2024
REVISION- Notable revisions: Prescriber Requirements	Q4 2023
REVISION- Notable revisions: Products Affected Required Medical Information Continuation of Therapy Duration of Approval Prescriber Requirements Age Restrictions Quantity HCPCS Code and Description Available Dosage Forms References	Q2 2023
REVISION- Notable revisions: Required Medical Information Products Affected	Q2 2022
Q2 2022 Established tracking in new format	Historical changes on file