

Continuous Glucose Monitors (CGMs) Prescription Products

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

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Summary

Diabetes mellitus (DM) (commonly referred to as diabetes) is a chronic (long-term) medical condition characterized by high blood glucose (sugar). This may be because the pancreas (an organ in the belly) does not make enough insulin (a hormone), or because the body is not responding to insulin the way it should (insulin insensitivity). Insulin helps glucose get into cells in the body, giving it energy. With diabetes, sugar builds up in the blood because the body stops responding to insulin, or because there is not enough of it. Inadequate glycemic control can lead to serious complications including cardiovascular disease, nephropathy, retinopathy, and neuropathy. The goal of diabetes management is to maintain blood glucose levels as close to the normal range as possible to prevent or delay complications.

Diabetes is broadly grouped into two major types:

- Type 1 diabetes mellitus - The pancreas produces little or no insulin.
- Type 2 diabetes mellitus - The body's cells do not respond to insulin the way they should; sometimes, the pancreas does not make enough insulin.

Managing diabetes necessitates regular monitoring and treatment, which often includes lifestyle adjustments, self-care, and medication to regulate blood glucose levels and reduce the risk of complications. Plan members diagnosed with Type 1 or Type 2 diabetes who meet specific medical necessity criteria and adhere to the American Diabetes Association (ADA) Standards of Care may be eligible for certain supplies and equipment covered by the plan, such as blood sugar monitoring tools and insulin injection devices. Those with advanced disease or requiring more frequent insulin administration may qualify for continuous glucose monitoring (CGM) and specialized insulin delivery systems.

Continuous glucose monitoring (CGM) is one method to monitor blood sugar for members who need it. CGMs check blood sugar about every one to five minutes, show the reading, and alerts members when blood sugar is not within the defined range. CGMs allow members to use the measurement, pattern or trends, to make better decisions about lifestyle or medication changes. There are different types of CGMs, such as:

- Professional CGM[#] - for use at prescriber's offices, usually a specialist in managing diabetes. They may also be given to members for a short time (e.g. a few days) in order to measure and evaluate trends. These are products such as Freestyle Libre Pro, Dexcom G6 Pro, and iPro2 Professional.
- Combination CGMs and external insulin pumps[#] - integrated with an external insulin pump, making available technology and functionality from both devices available to the member. These are products such as Tandem T:slim X2 systems (using Dexcom G6/7 or Freestyle Libre 2 Plus CGM sensors), Medtronic MiniMed 630G (using Guardian Sensor 3), or MiniMed 780G (using Guardian Sensor 4 or Instinct Sensor).

[#]not covered by Pharmacy Benefit. May be covered via Medical Benefit; please refer to Medical Clinical Guideline (CG029) - Insulin Delivery Systems and Continuous Glucose Monitoring.

- Stand-alone CGM - a personal system for long-term use, providing ongoing measurements of blood sugar levels, and readily available data.
- Over-the-Counter Continuous Glucose Monitoring Systems (OTC CGMs) - devices that have been cleared by the FDA for sale without a prescription. They are designed to help certain individuals monitor their glucose levels. OTC CGMs are not in-scope for this Oscar Clinical Guideline. Coverage of OTC CGMs, if any, depends on a member's specific benefit policy. Members should refer to their applicable benefit plan document to determine benefit availability and the terms and conditions of coverage for OTC CGMs.

NOTE: This Pharmacy Clinical Guideline is specific to only stand-alone prescription CGMs; examples of available, commonly prescribed products (not all-inclusive) are listed below in Table 1: Stand-alone Prescription CGM Systems.

- For information on medical necessity criteria of medical nutrition counseling, please refer to the Plan's Medical Clinical Guideline: Medical Nutrition Therapy (CG010).
- For information on medical necessity criteria of diabetes equipment and supplies, please refer to the Plan's Medical Clinical Guideline: Diabetes Equipment and Supplies (CG028).
- For the Plan's Medical Clinical Guideline of professional diagnostic or short-term continuous glucose monitoring and insulin pump delivery systems, please refer to the Plan's Medical Clinical Guideline: Insulin Delivery Systems and Continuous Glucose Monitoring (CG029).
- The Plan also covers home glucose monitors and products for self-monitoring of blood sugar as an alternative to CGMs. Please contact CVS/Caremark, the Plan's Prescription Benefit Manager, to obtain a standard blood glucose meter from the preferred brand.
- Coverage for OTC CGMs, if any, is determined by a member's specific benefit plan.

Table 1: Stand-alone Prescription CGM Systems

CGM System	FDA-approved or cleared for	Components	Use Life
Formulary Agents*			
Dexcom G6	≥ 2 years of age or older Type 1 and Type 2 Diabetes Mellitus	Receiver	1 year
		Sensor	Up to 10 days per sensor
		Transmitter	90 days
Dexcom G7	≥ 2 years of age or older Type 1 and Type 2 Diabetes Mellitus	Receiver	3 years (for typical use)
		Sensor	Up to 10 days per sensor
	≥ 18 years of age or older	Sensor	Up to 15 days per sensor

CGM System	FDA-approved or cleared for	Components	Use Life
	Type 1 and Type 2 Diabetes Mellitus		
Non-Formulary Agents*²			
Freestyle Libre 2	≥ 4 years of age or older	Sensor	Up to 14 days per sensor
	Type 1 and Type 2 Diabetes Mellitus	Reader	3 years (for typical use)
FreeStyle Libre 2 Plus	≥ 2 years of age or older	Sensor	Up to 15-days per sensor
	Type 1 and Type 2 Diabetes Mellitus		
Freestyle Libre 3	≥ 4 years of age or older	Sensor	Up to 14 days per sensor
	Type 1 and Type 2 Diabetes Mellitus	Reader	3 years (for typical use)
FreeStyle Libre 3 Plus	≥ 2 years of age or older	Sensor	Up to 15-days per sensor
	Type 1 and Type 2 Diabetes Mellitus		
Freestyle Libre 14-day	≥18 years of age or older	Sensor	Up to 14 days per sensor
	Type 1 and Type 2 Diabetes Mellitus	Reader	3 years (for typical use)
Medtronic Guardian Connect	14 to 75 years old	Guardian Sensor	Up to 7 days per sensor
	Type 1 and Type 2 Diabetes Mellitus	Guardian Connect Transmitter	Can be cleaned up to 122 times or one year, whichever comes first; then must be discarded
Senseonics Eversense 365	≥ 18 years of age or older	Eversense 365 Sensor [#]	365 days
	Type 1 and Type 2 Diabetes Mellitus	Transmitter	1 year
Medtronic Simplera	≥ 18 years of age or	Sensor	Up to 6-7 days per

CGM System	FDA-approved or cleared for	Components	Use Life
System	older Type 1 and Type 2 Diabetes Mellitus		sensor

**The Plan may review all requests made under the Medical or Pharmacy benefit against specific prior authorization criteria, as applicable and at its discretion. Products considered Formulary or Preferred for the Plan may still require a clinical prior authorization review. The Formulary status of these medications may change over time. Always refer to the member's Plan current Formulary for the most up-to-date information.*

‡Subject to Plan's Non-Formulary Products Criteria (PG069).

#The sensor insertion and removal procedures must be performed by a healthcare provider.

NOTE: This table provides a general overview of stand-alone prescription CGM systems for informational purposes only.

- It is not exhaustive and does not reflect all potential variations among devices. Features may vary by specific device and manufacturer. Always refer to the most up-to-date FDA-approved/cleared labeling.
- The Plan requires that members meet specific medical necessity criteria for coverage of Continuous Glucose Monitoring Systems (CGMS). This includes demonstrating inability to use, or documented trial and failure of, the Formulary and preferred system(s) before considering non-preferred or non-formulary options.
 - The order of CGM systems in this table does not indicate preference or tier status.
 - For specific coverage information, please refer to the applicable formulary and the member's benefit plan documents.

Definitions

“Blood Glucose” is the main sugar found in the blood and the body's main source of energy. It is also called glucose or blood sugar. The blood level of glucose is noted in milligrams per deciliter (mg/dL). When blood sugar is too high for long periods of time, complications can occur as a result of blood vessel damage.

“Blood Glucose Monitors” are small, portable machines used to check blood glucose levels in the ambulatory setting. A member will prick his/her fingertip and place a small sample of blood into the device for a glucose reading. There are a number of different types of blood glucose monitors for specialized situations, such as those for members with visual impairments.

“Continuous Glucose Monitoring (CGM)” serves as an alternative to self-monitoring of blood glucose (SMBG) with a home glucose monitor for patients who have diabetes and require multiple daily measurements.

“Documentation” refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

“External Continuous Subcutaneous Insulin Infusion (CSII) Pumps” or “Insulin Infusion Pumps” are non-implantable insulin-delivery devices that can be worn on a belt, kept in a pocket, or attached directly to the skin. An insulin pump connects to narrow, flexible plastic tubing that ends with a needle inserted just under the skin. Users set the pump to give a basal amount of insulin continuously throughout the day. Pumps release bolus doses of insulin (several units at a time) at meals and at times when blood glucose is too high, based on programming done by the user. Insulin infusion pumps serve as an alternative to multiple daily injections of insulin. The infusion cannula should be changed every 2-3 days to avoid lipid hypertrophy at the infusion site. Insulin infusion pumps can be differentiated by programmable/non-programmable, disposable/reusable, and subcutaneous/transdermal/implantable.

“Gestational Diabetes Mellitus (GDM)” is a type of diabetes mellitus that develops only during pregnancy and usually disappears upon delivery, but increases the risk that the mother will develop diabetes later. GDM is managed with meal planning, activity, oral agents, and, in some cases, insulin.

“Hemoglobin A1c (HbA1c)” is a test that measures a person's average blood glucose level over the past 2 to 3 months. It is also known as “A1c” or “glycosylated hemoglobin”. A1c should be measured at least twice annually for stable glycemic control and at least quarterly for unstable glycemic control. A1c test results may be affected by age, certain conditions, ethnicity, genetic traits, and pregnancy; the ADA recommends that treating providers review for discrepancies between A1c results and blood glucose results.

“Hyperglycemia” is excessive blood glucose. Fasting hyperglycemia is blood glucose above a desirable level after a person has fasted for at least 8 hours. Postprandial hyperglycemia is blood glucose above a desirable level 1 to 2 hours after a person has eaten.

“Hypoglycemia” is a condition that occurs when one's blood glucose is lower than normal, usually less than 70 mg/dL. Signs include hunger, nervousness, shakiness, perspiration, dizziness or lightheadedness, sleepiness, and confusion. If left untreated, hypoglycemia may lead to unconsciousness. Hypoglycemia is treated by consuming a carbohydrate-rich food such as a glucose tablet or juice. It may also be treated with an injection of glucagon if the person is unconscious or unable to swallow.

“Hypoglycemia Unawareness” is a state in which a person does not feel or recognize the symptoms of hypoglycemia. People who have frequent episodes of hypoglycemia may no longer experience the warning signs of it.

“Insulin” is a hormone made by the beta cells of the pancreas. Insulin allows glucose to enter the cells in the body for use in energy production, and when it is inadequate, the sugar remains in the blood leading to diabetes. There are a variety of oral and parenteral medications that can increase insulin production, increase the body’s sensitivity to existing insulin and reduce blood sugar. Insulin can also be injected or infused when lifestyle changes and non-insulin medications are inadequate.

“[s]” indicates state mandates may apply.

“Type 1 Diabetes” is an autoimmune condition that occurs when the beta cells of the pancreas are unable to produce enough insulin and therefore blood glucose cannot enter cells to be used for energy. Type 1 diabetes is often referred to as “insulin-dependent” because these patients require insulin daily to maintain their blood glucose at acceptable levels.

“Type 2 Diabetes” is a condition that occurs when either the pancreas doesn't produce enough insulin or the body cells become resistant to insulin. Type 2 diabetes is much more common than Type 1, and is often treated with combinations of lifestyle changes and non-insulin medications, although insulin can be required later in the disease course. Many individuals with Type 2 Diabetes are “insulin-requiring”.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Continuous Glucose Monitoring System

The Plan considers Continuous Glucose Monitoring Systems (CGMS) and its components medically necessary when ALL of the following criteria are met:

1. The requested product has received U.S. Food and Drug Administration (FDA) approval/clearance AND is age-appropriate for the member; *AND*
2. The member has a documented diagnosis of diabetes mellitus; *AND*
3. Long-term continuous glucose monitoring is needed for the member’s diabetes management, as evidenced by clinical documentation in the past 6 months showing ALL of the following:
 - a. The member requires blood glucose checks daily; *and*
 - b. The member meets at least ONE (1) of the following:
 - i. Type 1 diabetes; *or*
 - ii. Type 2 diabetes treated with insulin who have hemoglobin A1c above goal, despite appropriate changes in insulin therapy and compliance with the treatment plan; *or*

- iii. Type 2 diabetes treated with insulin with hyperglycemic excursions, despite appropriate changes in insulin therapy and compliance with the treatment plan; *or*
 - iv. Pregnant; *or*
 - v. Problematic hypoglycemia, defined as having a history of:
 - 1. Frequent/severe hypoglycemia; *or*
 - 2. Nocturnal hypoglycemia; *or*
 - 3. Hypoglycemia unawareness; *or*
 - 4. Severe hypoglycemia (≥ 2 episodes with blood glucose < 54 mg/dL in the past 30 days); *or*
 - 5. The member is on a medication that increases the risk of hypoglycemia (i.e., insulin therapy, sulfonylureas); *AND*
4. The requested product is for ONE (1) of the following:
- a. The Plan's preferred CGMS; *or*
 - b. A non-formulary CGMS, *AND* the member meets BOTH of the following criteria:
 - i. The member is unable to use or has tried and failed ALL of the Plan's Formulary CGMS; *and*
 - ii. IF the request is for, or a component of, the Senseonics Eversense 365 system, ALL of the following are met:
 - 1. The member is 18 years of age or older; *and*
 - 2. The member has inadequate glycemic control despite compliance, with trial and failure of ONE (1) of the following:
 - a. Standard blood glucose monitors with frequent self-monitoring finger sticks; *or*
 - b. Flash glucose monitoring; *or*
 - c. Continuous glucose monitoring (non-implantable); *or*
 - d. Allergy to adhesive or other materials in non-implantable CGM devices; *and*
 - 3. The insertion and removal of the glucose sensor in the upper arm will be conducted by a healthcare practitioner; *and*
 - 4. The member meets ALL of the following:
 - a. No evidence of being critically ill or hospitalized; *or*
 - b. No evidence of expecting to undergo an MRI (magnetic resonance imaging) procedure[‡] within 365 days for Eversense 365; *or*
- [‡]*NOTE: The Eversense Smart Transmitter is considered "MR Unsafe" and MUST BE REMOVED before undergoing an MRI procedure. The Eversense Sensor is considered "MR Conditional" under specific conditions. MRI staff should be informed about implanted sensors before any MRI procedure.*

- c. No evidence of another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents); *or*
- d. No evidence of history of dexamethasone or dexamethasone acetate contraindication, or allergies to systemic glucocorticoids (excluding topical, optical or nasal, but including inhaled); *or*
- e. No evidence of needing mannitol or sorbitol intravenously, or as a component of an irrigation solution or peritoneal dialysis solution; *or*
- f. No evidence of pregnancy or nursing, unless the potential benefits of CGM use outweigh the risks, as determined by the prescribing physician; *or*
- g. No evidence of receiving immunosuppressant therapy, chemotherapy, or anticoagulant therapy, unless specifically approved by the prescribing physician in consultation with the healthcare practitioner performing the sensor insertion.

If the above prior authorization criteria are met, the requested Continuous Glucose Monitoring System and its components will be approved as follows:^(s)

- For non-pregnant members, approve for up to 12 months
- For pregnant members, approve up through the end of pregnancy plus 4 weeks postpartum in accordance with the expected delivery date

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Continuous Glucose Monitoring System

The Plan considers Continuous Glucose Monitoring Systems and its components medically necessary (including for members who have been on the CGMS prior to enrollment with the Plan) when ALL of the following criteria are met:

1. The member continues to meet the above applicable **Initial Authorization** criteria; *AND*
2. There is documented provider evaluation within the last 6 months that demonstrates the member's adherence to their diabetic treatment plan and devices. This evaluation should assess the member's compliance with the prescribed treatment regimen and use of the CGMS, defined as documentation indicating ONE (1) of the following:
 - a. Confirmed improvement in glycemic management or time in range compared to previous fingerstick or CGM monitoring alone. This improvement should be documented and show that the CGMS has contributed to better glycemic control for the member, such as:
 - i. Sustained reduction in HbA1c of $\geq 0.5\%$; *or*

- ii. Increased in time in range (e.g., time with glucose levels between 70-180 mg/dL); *or*
- iii. Reduced glycemic variability; *or*
- iv. Decreased frequency or severity of hypoglycemic episodes; *or*
- b. The member is effectively utilizing the CGM, defined as sensor wear of more than 70% of the time; *or*
- c. The member is consistently using the CGMS as intended and benefiting from its continuous monitoring capabilities.

If the above prior authorization criteria are met, the requested Continuous Glucose Monitoring System and its components will be approved for up to 12 months.^[5]

Medical Necessity Criteria for Requests to Switch Continuous Glucose Monitoring Systems

The Plan considers requests to switch Continuous Glucose Monitoring Systems medically necessary if the member meets ONE (1) of the following:

1. The member has an allergy or reaction to their current CGM system (CGMS) adhesive or components that is unable to be managed or resolved; *OR*
2. The member requires a switch to a CGMS compatible with their insulin pump or automated insulin delivery system; *OR*
3. For members enrolled in an Oscar-designated disease management program - the member requires a switch to a CGMS meeting designated program requirements (i.e., switch their non-Dexcom Glucose Monitor to a Dexcom branded CGM device).

If the above switch criteria are met, the requested replacement Continuous Glucose Monitoring System and its components will be approved for the remaining duration of the member's current authorization period.^[5]

Exception Criteria for Additional Receivers/Readers (see Table 1: Stand-alone Prescription CGM Systems)

The Plan recognizes that there may be situations where an additional receiver/reader for a covered stand-alone Continuous Glucose Monitoring (CGM) system is needed prior to the 3-year replacement period for select products. In such cases, the following criteria must be met:

1. The currently owned receiver/reader must be non-functional and unable to be repaired or replaced by the manufacturer. Documentation should clearly indicate that the receiver/reader is no longer operational and cannot be fixed or replaced.
2. The member or healthcare provider must have made reasonable attempts to troubleshoot and resolve the issue with the non-functional receiver/reader. Documentation should demonstrate the efforts made to troubleshoot the device and the inability to repair or replace it.

NOTE: Replacement is limited to one receiver/reader per 3-year. Exceptions may be considered for special populations, such as children who may accidentally damage the device within the 3-year period.

Experimental or Investigational / Not Medically Necessary^[5]

Continuous Glucose Monitoring Systems and its components for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Additionally, the Plan does not consider medically necessary the replacement or repair of units or associated equipment when lost or damaged due to neglect or improper care.

Appendix

A. Over-the-Counter Continuous Glucose Monitoring Systems (OTC CGMs)

Recent FDA clearances have introduced over-the-counter (OTC) Continuous Glucose Monitoring Systems (CGMs) to the market. OTC CGMs are continuous glucose monitoring systems that can be purchased without a prescription. They are generally designed for use by individuals aged 18 and older who do not use insulin to manage their diabetes.

- OTC CGMs are not covered under this clinical policy. Coverage of OTC CGMs, if any, depends on a member's specific benefit policy. Members should refer to their applicable benefit plan document to determine benefit availability and the terms and conditions of coverage for OTC CGMs.

Table 2: Key Differences from Prescription CGMs

Feature	OTC CGMs	Prescription CGMs
User Age	≥18 years	Varies (may include pediatric use)
Insulin Use	Not intended for insulin users	Often indicated for insulin users
Glucose Range	May be limited	Typically broader
Alerts	Generally no alerts	May include customizable alerts
Data Sharing	May have limited options	Often include robust sharing features, may require third party or additional applications

Feature	OTC CGMs	Prescription CGMs
Integration	Not for use with insulin delivery systems	May integrate with insulin pumps/AID systems

NOTE: This table provides a general comparison between OTC and prescription CGMs for informational purposes only. It is not exhaustive and does not reflect all potential differences or variations among devices. Features may vary by specific device and manufacturer. This information does not constitute medical advice or endorsement of any particular product. Always consult with a healthcare professional for personalized advice on glucose monitoring options.

Table 3: FDA-Cleared OTC CGM Devices

Feature	Dexcom Stelo Glucose Biosensor System	Abbott Lingo Glucose System	Abbott Libre Rio Continuous Glucose Monitoring System
Intended Use	Adults 18 years and older not on insulin	Adults 18 years and older not on insulin (not necessarily intended for those with diabetes)	Non-insulin using persons age 18 and older (not necessarily intended for those with diabetes)
Sensor Life	Up to 15 days	Up to 14 days	Up to 14 days
Glucose Range	55-200 mg/dL	40-400 mg/dL	40-400 mg/dL
Special Features	<ul style="list-style-type: none"> - Readings updated every 15 minutes - Extended 12-hour grace period after 15 days 	<ul style="list-style-type: none"> - Helps detect euglycemic and dysglycemic glucose levels - May help users understand lifestyle impacts on glucose 	<ul style="list-style-type: none"> - Detects trends and tracks patterns - Aids in detection of euglycemia, hyperglycemia, and hypoglycemia
FDA Clearance	K234070	K233655	K233861

NOTE: This table provides a summary of FDA-cleared OTC CGM devices as of October 2024 for informational purposes only. It is not intended to be a comprehensive comparison or to recommend any particular device. Information is based on publicly available data and may not reflect the most current product specifications or features. These devices are not covered under this clinical policy, and their inclusion here does not imply coverage or endorsement. Members should consult the official product documentation, their healthcare provider, and their benefit plan for the most up-to-date and relevant information regarding these devices and their potential use.

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