Continuous Glucose Monitors (CGMs)

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.

Summary

Diabetes mellitus (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 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. Diabetes is broadly grouped into two types:

- Type 1 diabetes - the pancreas make no insulin, or a very small amount
- Type 2 diabetes - cells in the body do not respond to insulin the way they should; sometimes, the pancreas also does not make enough insulin

Diabetes is usually managed by eating healthy foods, getting plenty of exercise, and sometimes with medicines. Medicines are used to either control blood sugar, or to lower the chance of problems that can happen in the future because of diabetes. These medications can be insulin itself, or medications

that help the body make more insulin or help insulin do its job. In addition, Plan members who have been diagnosed with Type 1 or 2 DM, and meet certain medical necessity criteria and standards of care developed by the American Diabetes Association (ADA), may be eligible for specific supplies and equipment subject to plan benefits, such as those used to monitor blood sugar and inject insulin. Members with more advanced disease or those requiring more frequent insulin may qualify for continuous glucose monitoring and specialized insulin delivery systems.

Continuous glucose monitoring (CGM) is a new way 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 CGM sensors) or Medtronic MiniMed 630G/670G (using Guardian Sensor 3).
- Stand-alone CGM - a personal system for long-term use, providing ongoing measurements of blood sugar levels, and readily available data.

  [#]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.

NOTE: This Pharmacy Clinical Guideline is specific to only stand-alone CGMs; examples of available, commonly prescribed products (not all-inclusive) are listed below in **Table 1: Stand-alone 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 continuous glucose monitoring, implantable continuous glucose monitoring, and insulin infusion pumps, 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.

Table 1: Stand-alone CGM Systems

CGM System	FDA-approved or cleared for	Components	Use Life
Dexcom G6	at least two years old	Receiver	1 year
		Sensor	10 days per sensor
		Transmitter	90 days
Dexcom G7	at least two years old	Receiver	about 3 years
		Sensor	10 days per sensor
Freestyle Libre 2	at least four years old	Sensor	14 days per sensor
		Reader	about 3 years
Freestyle Libre 3	at least four years old	Sensor	14 days per sensor
Freestyle Libre 14-day	≥18 years old	Sensor	14 days per sensor
		Reader	about 3 years
Medtronic Guardian Connect	between the ages of 14 and 75 years old	Guardian Sensor 3	7 days per sensor
		Guardian Connect Transmitter	can be cleaned up to 122 times or one year, whichever comes first
Senseonics Eversense & Eversense E3	≥18 years old	Eversense Sensor*	90 days
		Eversense E3 Sensor*	180 days
		Transmitter	1 year

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

NOTE: The Plan requires that members be unable to use, or have tried and failed the Formulary and preferred system(s) first.

Definitions

"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.

"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".

"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.

"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.

Medical Necessity Criteria for Authorization

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

Medical Necessity Criteria for Initial Authorization

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

1. The requested device is age-appropriate for the member based on the U.S. Food and Drug Administration (FDA) approval/clearance; ***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:
    a. The member has documented adherence to diabetic treatment plan and can be trained to use a CGM; ***and***
    b. The member consistently checks blood glucose at least 3 times daily; ***and***
    c. The member meets at least ONE of the following:
        i. Type 1 diabetes; ***or***
        ii. Type 2 diabetes treated with basal insulin who have hemoglobin A1c above goal, despite appropriate changes in insulin therapy and compliance with the treatment plan; ***or***
        iii. On intensive insulin therapy, defined as 3 or more injections of insulin per day or the use of an insulin pump; ***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); ***AND***
4. The requested product is for **ONE** of the following:
    a. The Plan's preferred CGMS; ***or***
    b. The Plan's non-preferred CGMS **AND** the member is unable to use, or has tried and failed the Plan's preferred CGMS; ***or***
    c. A non-formulary CGMS, **AND** the member meets **BOTH** of the following criteria:
        i. 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 system, **ALL** of the following:

1. The member has inadequate glycemic control despite compliance, with trial and failure of **ONE** 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***
2. The insertion of the glucose sensor in the upper arm will be conducted by a healthcare practitioner; ***and***
3. The member does not have ANY of the following contraindications:
    a. Critically ill or hospitalized***; or***
    b. Expecting to undergo an MRI (magnetic resonance imaging) procedure within 90-days for Eversense or 180-days for Eversense E3 (Eversense sensor and transmitter are incompatible and must be removed before MRI procedure)***; or***
    c. Has another active implantable device, e.g., an implantable defibrillator (passive implants are allowed, e.g., cardiac stents)***; or***
    d. History of dexamethasone or dexamethasone acetate contraindication, or allergies to systemic glucocorticoids***; or***
    e. Need mannitol or sorbitol intravenously, or as a component of an irrigation solution or peritoneal dialysis solution***; or***
    f. Pregnant or nursing***; or***
    g. Receiving immunosuppressant therapy, chemotherapy, or anticoagulant therapy.

<u>If the above prior authorization criteria are met, the requested Continuous Glucose Monitoring System and its components will be approved as follows:</u>

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

Medical Necessity Criteria for Reauthorization

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

1. The member continues to meet all 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 ANY 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 ≥ 0.5%
        ii. Increased time with glucose levels between 70-180 mg/dL
        iii. Reduced glycemic variability
        iv. Decreased frequency or severity of hypoglycemic episodes
    b. the member is effectively utilizing the CGM, defined as sensor wear of more than 70% of the time
    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 12 months.

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** of the following:

1. The member has an allergy or reaction to their current CGM system adhesive or components that is unable to be managed or resolved; ***OR***
2. The member requires a switch to a CGM system 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.

Exception Criteria for Additional Receivers/Readers (*see Table 1: Stand-alone 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. In such cases, documentation should clearly demonstrate that the monitoring needs of the individual cannot be adequately met with the approved replacement limit.

Experimental or Investigational / Not Medically Necessary

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.

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