PRIOR AUTHORIZATION POLICY

POLICY: Diabetes – Continuous Glucose Monitoring Systems Prior Authorization Policy

- Dexcom G6 CGM System – Dexcom
- Dexcom G7 CGM System – Dexcom
- Eversense E3 CGM System – Ascensia/Senseonics
- Freestyle Libre CGM System – Abbott
- Freestyle Libre 2 CGM System – Abbott
- Freestyle Libre 3 CGM System – Abbott
- Freestyle Libre 2 Plus CGM System – Abbott
- Freestyle Libre 3 Plus CGM System – Abbott
- Guardian Connect CGM System – Medtronic
- Guardian 4 CGM System – Medtronic

REVIEW DATE: 01/29/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

The products targeted in this policy are continuous glucose monitoring (CGM) systems. Freestyle Libre and Freestyle Libre 2 are considered intermittently scanned CGM (isCGM) systems, whereas the other devices are considered real-time CGM (rtCGM) systems. Of note, throughout the policy, the term CGM "system" refers to all applicable components, including sensor, transmitter/reader, and receiver.

Most CGM systems are designated as integrated CGM (iCGM), a higher standard set by the FDA for integration with other digitally connected devices.[1] Dexcom G6, Dexcom G7, Eversense E3, FreeStyle Libre 2 Plus, FreeStyle Libre 3 Plus, and

Guardian are FDA-approved for use with automated insulin delivery (AID) systems. Dexcom G6, Dexcom G7, and FreeStyle Libre 2 are approved for use with connected insulin pens.

Guidelines

The American Diabetes Association (ADA) Standards of Care (2025) comment on the role of rtCGM and isCGM in the management of diabetes.[1] CGM is recommended for patients with diabetes who are on any type of insulin therapy (level of evidence A for rtCGM, level of evidence C for youth, and level of evidence B for adults). In all cases, it is noted that the choice of device should be made based on the individual's circumstances, preferences, and needs. In adults with type 2 diabetes treated with glucose lowering medications other than insulin, CGM may be considered to achieve and maintain glycemic goals (level of evidence B). In pregnant patients, CGM can help to achieve glycemic goals for individuals with type 1 diabetes and may be beneficial for other types of diabetes in pregnancy.

When used in addition to blood glucose monitoring in diabetes and pregnancy, CGM can help to achieve glycemic goals (level of evidence A) and hemoglobin A_{1c} goal (level of evidence B) in patients with type 1 diabetes and pregnancy and may be beneficial for other types of diabetes in pregnancy (level of evidence E).[1] CGM is recommended in pregnancies associated with type 1 diabetes (level of evidence A) and when used in addition to blood glucose monitoring, achieving traditional pre- and post-prandial goals, rtCGM can reduce the risk of large for gestational age infants and neonatal hypoglycemia in pregnant patients with type 1 diabetes (level of evidence A). There are insufficient data to support the use of CGM in all pregnant patients with type 2 diabetes or gestational diabetes. The decision to use CGM in such patients should be individualized based on treatment regimen, circumstances, preferences, and needs. In pregnant patients with pre-existing type 1 diabetes, insulin should be used (level of evidence A); in pregnant patients with pre-existing type 2 diabetes, insulin is preferred for glycemic management (level of evidence B).

CGM is beneficial and recommended for individuals at high risk of hypoglycemia (level of evidence A).[1] Patients considered to be at high risk of hypoglycemia are a subset of patients at risk for hypoglycemia who either have a major hypoglycemia risk factor or have multiple other risk factors (determined by the health care professional). One of the major risk factors identified in the Standards of Care is a recent (within the past 3 to 6 months) level 2 or level 3 hypoglycemia event. Level 2 hypoglycemia is defined as a glucose value < 54 mg/dL. Level 3 hypoglycemia is defined as a severe event characterized by altered mental and/or physical status requiring assistance for treatment of hypoglycemia, irrespective of glucose level.

The American Association of Clinical Endocrinology (AACE) clinical practice guidelines regarding use of advanced technology in the management of persons with diabetes mellitus (2021) discuss CGM.[2] CGM is strongly recommended for all persons with diabetes treated with intensive insulin therapy, defined as three or more injections of insulin per day or the use of an insulin pump (Grade A; high strength of evidence). It is noted that CGM may be recommended for individuals with type 2 diabetes who

are treated with less intensive insulin therapy; however, the strength of evidence is lower (Grade B; intermediate strength of evidence).

The AACE consensus statement for type 2 diabetes (2023) notes in patients with type 2 diabetes on basal insulin, clinical trials have shown that CGM is associated with increased time in range, improved hemoglobin A_{1c}, and decreased hypoglycemia, including severe hypoglycemic events.[3]

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of the targeted continuous glucose monitoring systems in this policy. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

- **Dexcom G6 CGM System – Dexcom**
- **Dexcom G7 CGM System – Dexcom**
- **Eversense E3 CGM System – Ascensia/Senseonics**
- **Freestyle Libre CGM System – Abbott**
- **Freestyle Libre 2 CGM System – Abbott**
- **Freestyle Libre 3 CGM System – Abbott**
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- **Guardian Connect CGM System – Medtronic**
- **Guardian 4 CGM System – Medtronic**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Diabetes.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Patient is using an insulin regimen; OR
     Note: This includes patients on a basal insulin regimen, basal and prandial insulin regimen, prandial insulin regimen, or continuous subcutaneous insulin infusion (insulin pump).
   - **B)** Patient is taking a medication for glycemic control other than insulin AND meets ONE the following (i or ii):
     - **i. Initial Therapy:** Approve if the patient meets ONE of the following (a or b):
       - **a)** Patient had a level 2 hypoglycemia event in the past 6 months; OR
         Note: A level 2 hypoglycemia event is defined as a blood glucose value < 54 mg/dL.
       - **b)** Patient had a level 3 hypoglycemia event in the past 6 months; OR
         Note: A level 3 hypoglycemia event is defined as a severe event characterized by altered mental and/or physical status requiring assistance for treatment of hypoglycemia, irrespective of glucose level.

ii. **Patient is Currently Receiving a Continuous Glucose Monitoring System:** Approve if the patient meets ONE of the following (a or b):
   a) Patient had a level 2 hypoglycemia event in the 6 months prior to initial continuous glucose monitoring system prescription; OR
   Note: A level 2 hypoglycemia event is defined as a blood glucose value < 54 mg/dL.
   b) Patient had a level 3 hypoglycemia event in the 6 months prior to initial continuous glucose monitoring system prescription.
   Note: A level 3 hypoglycemia event is defined as a severe event characterized by altered mental and/or physical status requiring assistance for treatment of hypoglycemia, irrespective of glucose level.

2. **Diabetes in a Pregnant Patient.** Approve for 9 months.
   Note: This includes type 1 diabetes, type 2 diabetes, or gestational diabetes.

CONDITIONS NOT COVERED

- **Dexcom G6 CGM System – Dexcom**
- **Dexcom G7 CGM System – Dexcom**
- **Eversense E3 CGM System – Ascensia/Senseonics**
- **Freestyle Libre CGM System – Abbott**
- **Freestyle Libre 2 CGM System – Abbott**
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is(are) considered experimental, investigational or unproven for ANY other use(s); criteria will be updated as new published data are available.

REFERENCES

1. American Diabetes Association. Standards of care in diabetes – 2025. *Diabetes Care*. 2025;48(Suppl 1):S1-S359.
2. Grunberger G, Sherr J, Allende M, et al. American Association of Clinical Endocrinology clinical practice guideline: the use of advanced technology in the management of persons with diabetes mellitus. *Endocr Pract*. 2021;27(6):505-537.
3. Samson SL, Vellanki P, Blonde L, et al. American Association of Clinical Endocrinology consensus statement: comprehensive type 2 diabetes management algorithm – 2023 update. *Endocr Pract.* 2023:29:305-340.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Targeted Products:** Dexcom G4 Platinum Continuous Glucose Monitoring (CGM) System was removed. Guardian 4 CGM System was added.	01/17/2024

	Diabetes: The Note was updated to include prandial insulin regimen to the list of insulin regimens.	
Selected Revision	**Automation:** The following automation was added to the policy: If the patient has a claim for one insulin (any insulin) within the 130-day lookback period, the claim will adjudicate. Previously, there was no automation.	02/07/2024
Selected Revision	**Diabetes:** A new criterion was added to address a patient at high risk of hypoglycemia. Initial Therapy. A patient with a recent (within the past 6 months) level 2 or level 3 hypoglycemia event may be approved. Patient Currently Receiving a Continuous Glucose Monitoring System. A patient currently receiving a continuous glucose monitoring system may continue to receive a continuous glucose monitoring system if they had a level 2 or 3 hypoglycemia event within the 6 months prior to the initial prescription.	09/25/2024
Annual Revision	**Targeted Products:** The following products were removed from the policy (obsolete): Dexcom G5 CGM system and Eversense CGM system. The following products were added to the policy: Freestyle Libre 2 Plus CGM system and Freestyle Libre 3 Plus CGM system. **Diabetes in a Pregnant Patient:** A new criterion was added. This includes a patient with type 1 diabetes, type 2 diabetes, or gestational diabetes.	01/29/2025