



PRIOR AUTHORIZATION POLICY

POLICY: Diabetes – Continuous Glucose Monitoring Systems Prior Authorization Policy

- Dexcom G5 CGM System – Dexcom [obsolete 01/01/2022]
- Dexcom G6 CGM System – Dexcom
- Dexcom G7 CGM System – Dexcom
- Eversense CGM System – Ascensia/Senseonics [obsolete 01/04/2022]
- Eversense E3 CGM System – Ascensia/Senseonics
- Freestyle Libre CGM System – Abbott
- Freestyle Libre 2 CGM System – Abbott
- Freestyle Libre 3 CGM System – Abbott
- Guardian Connect CGM System – Medtronic
- Guardian 4 CGM System – Medtronic

REVIEW DATE: 01/17/2024; selected revision 02/07/2024

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.

Of note, the Dexcom G5 CGM System was discontinued by the manufacturer as of June 2020. Per the manufacturer, sensor supply for this system, as well as technical support, would not be guaranteed after December 31, 2020.

Guidelines

The American Diabetes Association (ADA) Standards of Care (2024) comment on the role of rtCGM and isCGM in the management of diabetes.¹ The use of CGM devices should be considered from the outset of the diagnosis of diabetes that requires insulin management. The use of rtCGM (level of evidence A) or isCGM (level of evidence B) should be offered for diabetes management in adults with diabetes on multiple daily insulin injections or continuous subcutaneous insulin infusion (CSII). These devices also should be offered in youth with type 1 diabetes on multiple daily insulin injections or CSII (level of evidence A for rtCGM; level of evidence E for isCGM). In youth with type 2 diabetes, rtCGM or isCGM should be offered to those on multiple daily injections or CSII (level of evidence E). The use of rtCGM (level of evidence A) or isCGM (level of evidence B) should also be offered for diabetes management in adults with diabetes on basal insulin. In all cases, it is noted that the choice of device should be made based on the individual's circumstances, preferences, and needs.

When used in addition to blood glucose monitoring in diabetes and pregnancy, CGM can help to achieve glycemic goals (level of evidence B).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).

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.

- **Dexcom G5 CGM System – Dexcom [obsolete 01/01/2022]**
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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 Indication

1. Diabetes. Approve for 1 year if the patient is using an insulin regimen.

Note: This includes patients on a basal insulin regimen, basal and prandial insulin regimen, prandial insulin regimen, or continuous subcutaneous insulin infusion (insulin pump).

CONDITIONS NOT COVERED

- **Dexcom G5 CGM System – Dexcom [obsolete 01/01/2022]**
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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 medical care in diabetes – 2024. *Diabetes Care*. 2024;47(Suppl 1):S1-S349.
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 Jun;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
Early Annual Revision	Diabetes: The criterion regarding use of insulin was updated to state that the patient is using an insulin regimen, with a Note that this includes patients on a basal insulin regimen, basal and prandial insulin regimen, or continuous subcutaneous insulin infusion (insulin pump). Previously, the criteria approved for patients on a basal and prandial insulin regimen or continuous subcutaneous insulin infusion, but not for patients on basal insulin.	01/11/2023
Selected Revision	Diabetes: The criterion was updated to remove the requirement that the patient has type 1 or type 2 diabetes.	11/08/2023
Annual Revision	Targeted Products: Dexcom G4 Platinum Continuous Glucose Monitoring (CGM) System was removed. Guardian 4 CGM System was added. Diabetes: The Note was updated to include prandial insulin regimen to the list of insulin regimens.	01/17/2024
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

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