

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 and 09/25/2024

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).

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.

Automation: If the patient has a claim for one insulin (any insulin) within the 130-day lookback period, the claim will adjudicate.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of the continuous glucose monitoring systems in this policy is recommended in those who meet the following criteria:

FDA-Approved Indication

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.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of the continuous glucose monitoring systems in this policy is not recommended in the following situations:

- 1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. American Diabetes Association. Standards of 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.