

PHARMACY COVERAGE GUIDELINE

CONTINUOUS GLUCOSE MONITORING (CGM) DEVICE IN INTERSTITIAL FLUID: DEXCOM G5 DEXCOM G6 FREESTYLE LIBRE MEDTRONIC SENSEONICS EVERSENSE Sensor/Holder/Smart Transmitter

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively “Service”) is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider’s judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member’s benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The “Criteria” section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member’s benefit plan.
- The “Description” section describes the Service.
- The “Definition” section defines certain words, terms or items within the policy and may include tables and charts.
- The “Resources” section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the [request form](#) and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

DEXCOM G5 CGM DEXCOM G6 CGM FREESTYLE LIBRE CGM

- **Criteria for initial and continuation of therapy:** Dexcom G5, Dexcom G6, and Freestyle Libre glucose monitoring in the interstitial fluid in considered **medically necessary** and will be approved with medical record documentation of **ALL** of the following criteria (**samples are not considered for continuation of therapy**):

ORIGINAL EFFECTIVE DATE: 02/01/2020 | ARCHIVE DATE: | LAST REVIEW DATE: 02/17/2022 | LAST CRITERIA REVISION DATE: 08/18/2022

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1. Individual has a confirmed diagnosis of **ONE** of the following:
 - a. Type 1
 - b. Type 2 on therapy for diabetes that cause hypoglycemia
 - c. Pregnant individual

2. Trial to any in the last 3 months is **ONE** of the following:
 - a. For **Dexcom G5 and Dexcom G6**:
 - i. Insulin

 - b. For **Freestyle Libre**:
 - i. Amylin Analog
 - ii. Incretin Mimetic Agent (or Glucagon-like peptide-1 agonist (GLP-1))
 - iii. Insulin
 - iv. Insulin Sensitizing Agents
 - v. Meglitinide Analogues
 - vi. Sodium-Glucose Co-Transporter 2 Inhibitors
 - vii. Sulfonylureas

3. The Continuous Glucose Monitoring (CGM) device is intended to replace the fingerstick blood glucose testing for diabetes treatment decisions

Approval duration: 12 months, unless approved for 72 hours

- Arizona statutory coverage mandates do not require coverage of continuous glucose monitoring devices unless **medically necessary**.

- Although rental of the device is **not eligible for coverage**, the professional services for consultation and review of data are **eligible for coverage** as evaluation and management (E/M) services with appropriate documentation.

- Continuous Glucose Monitoring (CGM) Device for the treatment of diabetes mellitus is considered **experimental or investigational** when any one or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement outside the investigational setting

These indications include, but are not limited to:

- Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, when appropriate.

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MEDTRONIC CGM

SENSEONICS EVERSENSE Sensor/Holder/Smart Transmitter

- **Criteria for initial therapy:** Medtronic CGM device and Senseonics Eversense Sensor/Holder/Smart Transmitter is considered **medically necessary** and will be approved with medical record documentation of **ALL** of the following criteria:
1. Prescriber is a physician or other prescribers specializing in diabetes or is in consultation with an Endocrinologist
 2. Individual has a confirmed diagnosis of **Type 1 Diabetes**
 3. Individual has failure, contraindication or intolerance to **ONE** of the following:
 - a. Freestyle Libre GCM
 - b. Dexcom G5 or Dexcom G6 GCM
 4. Individual has **ONE** of the following:
 - a. Recurrent, unexplained, unexpected severe hypoglycemia (blood glucose levels less than 50 mg/dl)
 - b. Hypoglycemia unawareness
 - c. Suspected post-prandial hyperglycemia
 - d. Recurrent diabetic ketoacidosis
 - e. Uses an external insulin infusion pump system
 - f. Short term use (72 hours) to determine baseline insulin levels prior to insulin pump initiation
 5. The Continuous Glucose Monitoring (CGM) device is intended to replace the fingerstick blood glucose testing for diabetes treatment decisions

Initial approval duration: 12 months, unless approved for 72 hours

- **Criteria for continuation of coverage (renewal request):** Medtronic CGM device and Senseonics Eversense Sensor/Holder/Smart Transmitter is considered **medically necessary** and will be approved when **ALL** the following criteria are met (**samples are not considered for continuation of therapy**):
1. Individual continues to be seen by a physician or other prescribers specializing in diabetes or is in consultation with an Endocrinologist
 2. Uses an external insulin infusion pump system
 3. Individual's condition responded while on therapy with response defined as **THREE** of the following:
 - a. Achieved and maintains HgA1C of 7%
 - b. There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes
 - c. There is no hypoglycemia unawareness
 - d. There is no post-prandial hyperglycemia
 - e. There has been a reduction in diabetic ketoacidosis

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4. The Continuous Glucose Monitoring (CGM) device is intended to replace the fingerstick blood glucose testing for diabetes treatment decisions

Renewal duration: 12 months

- Arizona statutory coverage mandates do not require coverage of continuous glucose monitoring devices unless **medically necessary**.
- Although rental of the device is **not eligible for coverage**, the professional services for consultation and review of data are **eligible for coverage** as evaluation and management (E/M) services with appropriate documentation.
- Continuous Glucose Monitoring (CGM) Device for the treatment of diabetes mellitus is considered **experimental or investigational** when any one or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement outside the investigational setting

These indications include, but are not limited to:

- Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, when appropriate.

Description:

Benefit Type:

Pharmacy Benefit:

DEXCOM G5
DEXCOM G6
FREESTYLE LIBRE

Medical Benefit:

MEDTRONIC
SENSEONICS EVERSENSE Sensor/Holder/Smart Transmitter

Regular glucose monitoring is one way people with diabetes can learn more about their condition that allows them to make important decisions about medication dosage, exercise, and diet. Information on trends in glucose levels may benefit individuals with diabetes who are inadequately control, despite compliance with best practices.

Tight glucose control in patients with diabetes has been associated with improved health outcomes. Several devices are available to measure glucose levels automatically and frequently (e.g., every 5-10 minutes). Devices that measure glucose in the interstitial fluid are approved as adjuncts to traditional self-monitoring of blood glucose levels. These devices are used intermittently (short-term) basis or a continuous (long-term) basis.

Glucose monitoring of the interstitial fluid is another technique of automatically measuring glucose levels throughout the day to provide trends in glucose measurements. In contrast to traditional isolated blood glucose

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levels, these monitors test glucose levels without routine finger sticks. The monitor is worn on the arm or on the abdomen and it automatically measures glucose readings throughout the day.

The benefits of using CGM in diabetes for physicians and patients is derived from the ability to discover previously unknown hyper- and hypoglycemia (silent and symptomatic); measure glycemic control directly rather than through the use of a surrogate marker (hemoglobin A1C (HbA1C)); allows for the observation of a wide variety of metrics such as glycemic variability, percent of time within, below and above target glucose levels, severity of hypo- and hyperglycemia throughout the day and night; provide actionable information for healthcare providers from a CGM report; allows for better management of patients on hemodialysis; effectively and efficiently analyzes glycemic effects of new interventions; and as a behavior modification tool.

Continuous glucose monitoring (CGM) does not eliminate the need for at least occasional finger sticks. Consistent and reliable use of a CGM system can modestly improve glycemic control in adults with T1DM and T2DM.

Glucose trending information from CGM can be used to make insulin adjustments, there are fewer periods of hypoglycemia, there are significant reduction in HbA1C with use of CGM versus self-monitoring blood glucose (SMBG), and the mean number of finger sticks is reduced with use of CGM. CGM facilitates monitoring of time spent in the target glucose range (“time in range”) and can warn users if glucose is trending toward hypoglycemia or hyperglycemia. Individuals with T2DM not on prandial insulin who use CGM intermittently for 12 weeks significantly improve glycemic control at 12 weeks and the improvement without CGM is sustained during the 40-week follow-up period, compared with those who used only SMBG.

Resources:

1.01.20 BCBS Association Medical Policy Reference Manual. Continuous or Intermittent Monitoring of Glucose in the Interstitial Fluid. Issue date 11/2018

1.01.32 BCBS Association Medical Policy Reference Manual. Artificial Pancreas Device Systems. Review date 12/2017
Arizona Revised Statutes. Annotated sections 20-828, 20-1057, and 20-2325.

UpToDate: Self-monitoring of blood glucose in management of adults with diabetes mellitus. Current through Jan 2019

Cengiz E and Tamborlane WV. A tale of two compartments: interstitial verses blood glucose monitoring. *Diabetes Technol Therapeutics* 2009; 11 (Sup 1):11-16

Gandhi GY, Kovalaske M, Kudva Y, et al.: Efficacy of continuous glucose monitoring in improving glycemic control and reducing hypoglycemia: A systematic review and meta-analysis of randomized trials. *J Diabetes Sci Technol* 2011 July; 5 (4):952-965

Ehrhardt NM, Chellappa M, Walker S, et al.: The effect of real-time continuous glucose monitoring on glycemic control in patients with type 2 diabetes mellitus. *J Diabetes Sci Technol* 2011 May; 5 (3):668-675

Vigersky RA, Fonda SJ, Chellappa M, et al.: Short and long term effects of real time continuous glucose monitoring in patients with type 2 diabetes mellitus. *Diabetes Care* 2012 Jan; 35:32-38

Kim SK, Kim HJ, Kim T, et al.: Effectiveness of 3-day continuous glucose monitoring for improving glucose control in type 2 diabetic patients in clinical practice. *Diabetes Metab J* 2014; 38:449-455

Vigersky R, Shrivastav M. Role of continuous glucose monitoring for type 2 in diabetes management and research. *J Diabetes Complications*. 2017 Jan;31(1):280-287.

Danne T, Nimri R, Battelino T, et al.: International consensus on use of continuous glucose monitoring. *Diabetes Care* 2017 December; 40: 1631-1640



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Shrivastav M, Gibson W, Shrivastav R, et al.: Type 2 diabetes management in primary care: The role of retrospective, professional continuous glucose monitoring. *Diabetes Spectrum* 2018 Aug; 31(3): 279-287.

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