**PHARMACY COVERAGE GUIDELINES**
**SECTION: DRUGS**

**ORIGINAL EFFECTIVE DATE: 2/01/2020**
**LAST REVIEW DATE: 11/18/2021**
**LAST CRITERIA REVISION DATE: 11/18/2021**
**ARCHIVE DATE:**

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

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

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# CONTINUOUS GLUCOSE MONITORING (CGM) DEVICE IN INTERSTITIAL FLUID

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. **All requested data must be provided.** Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

## 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:

  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

  **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 IN INTERSTITIAL FLUID

- Dexcom G5, Dexcom G6, and Freestyle Libre for all other indications not previously listed is considered ***experimental or investigational*** and will not be covered when any one or more of the following criteria are met:

  1. Lack of final approval from the Food and Drug Administration;
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
  3. Insufficient evidence to support improvement of the net health outcome;
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; **or**
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, but are not limited to:
  a. Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration.

## 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

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

## CONTINUOUS GLUCOSE MONITORING (CGM) DEVICE IN INTERSTITIAL FLUID

- **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** of the following criteria are met:

  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
     a. Response is defined as **THREE** of the following:
        i. Achieved and maintains HgA1C of 7%
        ii. There has been a reduction in recurrent, unexplained, unexpected hypoglycemic episodes
        iii. There is no hypoglycemia unawareness
        iv. There is no post-prandial hyperglycemia
        v. There has been a reduction in diabetic ketoacidosis

  **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.

- Medtronic CGM device and Senseonics Eversense Sensor/Holder/Smart Transmitter for all other indications not previously listed is considered ***experimental or investigational*** and will not be covered when any one or more of the following criteria are met:

  1. Lack of final approval from the Food and Drug Administration;
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes;
  3. Insufficient evidence to support improvement of the net health outcome;
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; **or**
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, but are not limited to:
  a. Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration.

# CONTINUOUS GLUCOSE MONITORING (CGM) DEVICE IN INTERSTITIAL FLUID

**Description:**

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 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.

**Benefit Type**:

**Pharmacy Benefit**:

DEXCOM G5
DEXCOM G6
FREESTYLE LIBRE

**Medical Benefit**:

MEDTRONIC
SENSEONICS EVERSENSE Sensor/Holder/Smart Transmitter

## CONTINUOUS GLUCOSE MONITORING (CGM) DEVICE IN INTERSTITIAL FLUID

**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, Chellppa 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

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.