BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

CONTINUOUS GLUCOSE MONITORING (CGM) DEVICE IN INTERSTITIAL FLUID: DEXCOM 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/or 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 prior authorization 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.

Medical Necessity Requirements for DEXCOM and FREESTYLE LIBRE

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a physician specializing in diabetes or in consultation with an Endocrinologist

Indication
- **ONE** of the following:

- Type 1 diabetes mellitus
- Type 2 diabetes mellitus
- Gestational diabetes in pregnancy

Baseline Clinical Evaluation

- Diagnosis of diabetes is confirmed in medical records
- Device is intended to replace fingerstick blood glucose testing for diabetes treatment decisions

Alternative Therapies

- Trial in the last three months of **ANY** of the following:
  - Amylin analog (pramlintide)
  - Dipeptidyl Peptidase-4 Inhibitors (alogliptin, Januvia, Onglyza, others)
  - Glucagon-like peptide-1 agonist (exenatide, liraglutide, others)
  - Insulin (insulin glargine, insulin NPH, insulin lispro, others)
  - Insulin sensitizing agents (pioglitazone, metformin)
  - Meglitinide analogues (nateglinide, repaglinide)
  - Sodium-glucose co-transporter 2 inhibitors (canagliflozin, dapagliflozin, others)
  - Sulfonylureas (glipizide, glyburide, others)

Additional Requirements

- 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*** such 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:
  - Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  - Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  - Insufficient evidence to support improvement of the net health outcome; or
  - Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  - Insufficient evidence to support improvement outside the investigational setting
  - These indications include but are not limited to:
    1. Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 12 months or duration of gestational diabetes in pregnancy OR end of plan year

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Medical Necessity Requirements for MEDTRONIC and SENSEONICS EVERSENSE

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a physician specializing in diabetes or in consultation with an Endocrinologist

Indication

- Type 1 diabetes mellitus

Baseline Clinical Evaluation

- Diagnosis of diabetes is confirmed in medical records
- Device is intended to replace fingerstick blood glucose testing for diabetes treatment decisions
- **ONE** of the following:
  - Recurrent, unexplained, unexpected severe hypoglycemia (blood glucose levels less than 50 milligrams per deciliter)
  - Hypoglycemia unawareness
  - Suspected post-prandial hyperglycemia
  - Recurrent diabetic ketoacidosis
  - Uses an external insulin infusion pump system
  - Short term use (72 hours) to determine baseline insulin levels prior to insulin pump initiation

Alternative Therapies

- Failure, contraindication, or intolerance to **ANY** of the following:
  - Freestyle Libre Continuous Glucose Monitoring Device
  - Dexcom Continuous Glucose Monitoring Device

Additional Requirements

- 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*** such 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:
  - Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  - Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  - Insufficient evidence to support improvement of the net health outcome; or
  - Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  - Insufficient evidence to support improvement outside the investigational setting
  - These indications include but are not limited to:
    1. Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration

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Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes
  - Lab results
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration
- 12 months (unless approved for 72 hours for gestational diabetes) OR end of plan year

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Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by a physician specializing in diabetes or is in consultation with an Endocrinologist

Clinical Response
- Documentation of positive clinical response defined as **THREE** of the following:
  - Achieved and maintains Hemoglobin A1C of 7 percent
  - Reduction in recurrent, unexplained, unexpected hypoglycemic episodes
  - No hypoglycemia unawareness
  - No post-prandial hyperglycemia
  - Reduction in diabetic ketoacidosis

Adherence
- Uses an external insulin infusion pump system
- Adherence to the prescribed therapy regimen has been documented

Additional Requirements
- 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*** such 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:
  - Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  - Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  - Insufficient evidence to support improvement of the net health outcome; or
  - Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  - Insufficient evidence to support improvement outside the investigational setting
  - These indications include but are not limited to:
    2. Treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values that confirm safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Benefit Type:

Pharmacy Benefit:
DEXCOM
FREESTYLE LIBRE

Medical Benefit:
MEDTRONIC
SENSEONICS EVERSENSE Sensor/Holder/Smart Transmitter

Coding:

HCPCS: A4238, A4239, A9276, A9277, A9278, E2103

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.

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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 reductions 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:

Weinstock RS. Glucose monitoring in the ambulatory management of nonpregnant adults with diabetes mellitus. In: UpToDate, Hirsch RS, Rubinow K (Eds), UpToDate, Waltham MA.: UpToDate Inc. Available at http://uptodate.com. Literature current through November 2025. Topic last updated August 26, 2024. Accessed December 15, 2025.

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. Accessed January 17, 2019. Re-evaluated December 15, 2025.

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. Accessed February 21, 2019. Re-evaluated December 15, 2025.

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. Accessed February 20, 2019. Re-evaluated December 15, 2025.

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. Accessed January 17, 2019. Re-evaluated December 15, 2025.

Danne T, Nimri R, Battelino T, et al.: International consensus on use of continuous glucose monitoring. Diabetes Care 2017 December; 40: 1631-1640. Assessed January 17, 2019. Re-evaluated December 15, 2025.

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. Accessed January 17, 2019. Re-evaluated December 15, 2025.

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. Accessed February 22, 2019. Re-evaluated December 15, 2025.

El Sayed NA, Aleppo G, Aroda VR, et al: Diabetes Technology: Standards of c\Care in Diabetes – 2023. Diabetes Care 2023;46 (Suppl. 1): S111–S127 | https://doi.org/10.2337/dc23-S007. Accessed December 11, 2023. Re-evaluated December 15, 2025.