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 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.

Criteria:

DEXCOM CGM
FREESTYLE LIBRE CGM

- **Criteria for initial and continuation of therapy:** Dexcom 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)**:

    1. Individual has a confirmed diagnosis of **ONE** of the following:

   a. Type 1 diabetes mellitus

   b. Type 2 diabetes mellitus on therapy for diabetes that causes hypoglycemia

   c. Pregnant individual with gestational diabetes

2. There is documentation of a trial of **ANY** of the following in the last 3 months:
   a. Amylin analog (e.g., pramlintide)
   b. Glucagon-like peptide-1 agonist (GLP-1) (e.g., exenatide, liraglutide, others)
   c. Insulin (e.g., Insulin glargine, insulin NPH, insulin lispro, others)
   d. Insulin sensitizing agents (e.g., pioglitazone, metformin)
   e. Meglitinide analogues (e.g., nateglinide, repaglinide)
   f. Sodium-glucose co-transporter 2 inhibitors (e.g., canagliflozin, dapagliflozin, others)
   g. Sulfonylureas (e.g., glipizide, glyburide, others)

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 for gestational diabetes)

- 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 of the net health outcome; or
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*:

- 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 mellitus**

3. Individual has failure, contraindication or intolerance to **ANY** of the following:
   a. Freestyle Libre GCM
   b. Dexcom 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 for gestational diabetes)

- **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 has 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

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 of the net health outcome; or
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*:

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

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.

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:

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 2024. Topic last updated August 26, 2024. Accessed December 10, 2024.

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 10, 2024.

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 10, 2024.

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 10, 2024.

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 10, 2024.

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 10, 2024.

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 10, 2024.

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 10, 2024.

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 10, 2024.