

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

Continuous Glucose Monitoring Devices (CGMs)

Override(s)	Approval Duration
Prior Authorization	Receiver: One time Sensors and transmitters: 1 year

Continuous Glucose Monitoring Devices (CGMs) – including sensor, transmitter, receiver	Comments
Dexcom Product Line Freestyle Libre Product Line	Preferred
Eversense Product Line Medtronic Product Lines for the following products: <ul style="list-style-type: none"> • Enlite sensors • Guardian (monitors, receivers, sensors, transmitters) • Minimed Guardian sensor • Sof-sensor 	Non-Preferred

APPROVAL CRITERIA

Step Therapy for non-preferred agents

Requests for non-preferred continuous glucose monitoring devices and supplies (receiver, transmitter, sensor) must meet the following criteria:

- I. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance of one preferred continuous glucose monitor (Dexcom Product Line or Freestyle Libre Product Line); **OR**
- II. Individual utilized an insulin pump that is only compatible with a non-preferred continuous glucose monitor.

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Prior Authorization for all agents

Professional, intermittent, short-term use of continuous interstitial glucose monitoring devices as an adjunct to standard care may be approved when the following criteria are met:

- A. Individual is diagnosed with type 1 diabetes; **AND**
- B. Inadequate glycemic control despite compliance with frequent self-monitoring (*at least 4 times per day*) and including fasting hyperglycemia (greater than 150 mg/dL) or recurring episodes of severe hypoglycemia (less than 50 mg/dL). This poor control is in spite of compliance with multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
- C. Insulin injections are required 3 or more times per day or an insulin pump is used for maintenance of blood sugar control; **AND**
- D. Four or more fingersticks are required per day; **AND**
- E. Monitoring and interpretation are under the supervision of a physician; **AND**
- F. The device is only used for 6, 7, or 14 consecutive days on an appropriate, periodic basis.

Personal long-term use of continuous interstitial glucose monitoring devices as an adjunct to standard care may be approved for *any* of the following:

- A. Adults (greater than or equal to 25 years old) with type 1 diabetes who meet the following criteria:
 1. Inadequate glycemic control, demonstrated by HbA1c measurements between 7.0% and 10.0%, despite:
 - a. Compliance with frequent self-monitoring (*at least 4 times per day*); **AND**
 - b. Multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
 2. Insulin injections are required 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control; **OR**
- B. Individuals, regardless of age, with type 1 diabetes who meet the following criteria:
 1. Recurring episodes of severe hypoglycemia (less than 50 mg/dL); **AND**
 2. Inadequate glycemic control despite:
 - a. Compliance with frequent self-monitoring (*at least 4 times per day*); **AND**
 - b. Multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
 3. Insulin injections are required 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control; **or**
- C. Individuals with type 1 diabetes who are pregnant, during the course of the pregnancy, who meet the following criteria:
 1. Inadequate glycemic control despite compliance with frequent self-monitoring (*at least 4 times per day*) and including fasting hyperglycemia (greater than 150

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- mg/dL) or with recurring episodes of severe hypoglycemia (less than 50 mg/dL). This poor control is in spite of compliance with multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
2. Insulin injections are required 3 or more times per day or a medically necessary insulin pump is used for maintenance of blood sugar control; **AND**
 3. Four or more fingersticks are required per day.

The *replacement* of continuous interstitial glucose monitoring devices may be approved when the following criteria have been met:

- A. The device is out of warranty; **AND**
- B. The device is malfunctioning; **AND**
- C. The device cannot be refurbished.

Use of continuous interstitial glucose monitoring devices may not be approved for all other indications, including but not limited to:

- A. When the criteria above have not been met.
- B. Individuals with type 2 diabetes.

Replacement of currently functional and warranted continuous interstitial glucose monitoring devices may not be approved when the replacement of continuous interstitial glucose monitoring devices approval criteria (A, B, and C) above have not been met.

Key References:

1. American Diabetes Association. Standards of Care in Diabetes-2018. Diabetes Care. 2018; 41(Suppl 1):S1-S159.
2. Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 outpatient glucose monitoring consensus statement. Endocr Pract. 2016; 22(2):231-261.
3. Grunberger G, Bailey T, Camacho PM, et al.; Glucose Monitoring Consensus Conference Writing Committee. Proceedings from the American Association of Clinical Endocrinologists and American College of Endocrinology consensus conference on glucose monitoring. Endocr Pract. 2015; 21(5):522-533.
4. Fonseca VA, Grunberger G, Anhalt H, et al.; Consensus Conference Writing Committee. Continuous glucose monitoring: a consensus conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. Endocr Pract. 2016; 22(8):1008-1021
5. Handelsman Y, Bloomgarden ZT, Grunberger G, et al. American Association of Clinical Endocrinologists and American College of Endocrinology - clinical practice guidelines for developing a diabetes mellitus comprehensive care plan - 2015. Endocr Pract. 2015; 21(Suppl 1):1-87.
6. Klonoff DC, Buckingham B, Christiansen JS, et al. Continuous glucose monitoring: an Endocrine Society clinical practice guideline. J Clin Endocrinol Metab. 2011; 96(10):2968-2979.
7. Langendam M, Luijck YM, Hooft L, et al. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev. 2012;(1):CD008101.
8. Moy FM, Ray A, Buckley BS. Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. Cochrane Database Syst Rev. 2014;(4):CD009613.

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9. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes technology-continuous subcutaneous insulin infusion therapy and continuous glucose monitoring in adults: an Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016; 101(11):3922-3937.

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