

Continuous Glucose Monitoring Devices (CGMs)

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

Continuous Glucose Monitoring Devices (CGMs) – including sensor, transmitter, receiver	Comments
Freestyle Libre Product Line – CT and CO only	Preferred
Dexcom Product Line Freestyle Libre Product Line – all states except CT and CO 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

Product/Product Line	Quantity Limit
Dexcom G5 Receiver*	1 receiver per year (based on manufacturer warranty)
Dexcom G5 Transmitter	1 transmitter per 90 days
Dexcom G5 Sensor	4 sensors per 28 days
Dexcom G6 Receiver*	1 receiver per year (based on manufacturer warranty)
Dexcom G6 Transmitter	1 transmitter per 90 days
Dexcom G6 Sensor	3 sensors per 30 days
Dexcom G7 Receiver*	1 receiver per year (based on manufacturer warranty)
Dexcom G7 Sensor	3 sensors per 30 days

Freestyle Libre reader*	1 reader per year (based on manufacturer warranty)
Freestyle Libre 10 day sensor	3 sensors per 30 days
Freestyle Libre 14 day Reader*	1 reader per year (based on manufacturer warranty)
Freestyle Libre 14 day Sensor	2 sensors per 28 days
Freestyle Libre 2 Reader*	1 reader per year
Freestyle Libre 2 Sensor	2 sensors per 28 days
Freestyle Libre 3 Sensor	2 sensors per 28 days
Guardian Connect Transmitter*	2 transmitters per year
Guardian Sensor (3)	5 sensors per 30 days
Eversense Smart Transmitter*	1 transmitter per year

APPROVAL CRITERIA

Step Therapy for non-preferred agents

CT and CO only - 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 (Freestyle Libre Product Line); **OR**
- II. Individual utilized an insulin pump that is only compatible with a non-preferred continuous glucose monitor.

Prior Authorization for all agents

Initial requests for *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. Individuals greater than or equal to 14 years old with diabetes mellitus (any type) who meet the following criteria:
 1. Inadequate glycemic control, demonstrated by HbA1c measurements between 7.0% and 10.0%, despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
 2. Insulin injections are required multiple times daily or a medically necessary insulin pump is used for maintenance of blood sugar control; **OR**
- B. Individuals, regardless of age, with diabetes mellitus (any type) who meet the following criteria:

1. Recurring episodes of hypoglycemia; **AND**
 2. Inadequate glycemic control despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
 3. Insulin injections are required multiple times daily 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, including fasting hyperglycemia or with recurring episodes of hypoglycemia in spite of compliance with multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
 2. Insulin injections are required multiple times daily or a medically necessary insulin pump is used for maintenance of blood sugar control; **AND**
 3. Multiple blood glucose tests are required daily.

Continuation requests for CGM supplies may be approved if the following criteria are met:

- I. Individual met the initiation criteria at the time of the first request for the CGM device; **AND**
- II. Individual has seen improvement in diabetes management as a result of using the CGM; **AND**
- III. Individual has a CGM device that is compatible with requested supplies.

***Quantity Override:**

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:

- I. When the criteria above have not been met.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
4. Tamborlane WV, Beck RW, Bode BW, et al.; Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Continuous glucose monitoring and intensive treatment of type 1 diabetes. N Engl J Med. 2008; 359(14):1464-1476.
5. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Effectiveness of continuous glucose monitoring in a clinical care environment. Diabetes Care. 2010; 33(1):17-22.

6. Battelino T, Phillip M, Bratina N, et al. Effect of continuous glucose monitoring on hypoglycemia in type 1 diabetes. *Diabetes Care*. 2011; 34(4):795-800.
7. Heinemann L, Freckmann G, Ehrmann D, et al. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. *Lancet*. 2018; 391(10128):1367-1377.
8. American Diabetes Association. 7. Diabetes technology: Standards of Medical Care in Diabetes. *Diabetes Care* 2022 Jan; 45 (Supplement 1): S97-S112. <https://doi.org/10.2337/dc22-S007>. Accessed December 9, 2022.
9. Shatlin S, Phillip M. Hypoglycemia in type 1 diabetes: A still unresolved problem in the era of insulin analogs and pump therapy. *Diabetes Care*; 2008 Feb; 31(supplement 2): S121-S124. Available from: https://care.diabetesjournals.org/content/31/Supplement_2/S121.
10. Diabetes Control and Complications Trial Research Group (DCCT). Effect of intensive diabetes treatment on the development and progression of long-term complications in adolescents with insulin-dependent diabetes mellitus: Diabetes Control and Complications Trial. *J of Pediatr*. 1994; 125(2):177-188.
11. Feig DS, Donovan LE, Corcoy R, et.al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. *Lancet*. 2017 Nov 25;390(10110):2347-2359. doi: 10.1016/S0140-6736(17)32400-5. Epub 2017 Sep 15. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5713979/>.
12. Fonseca VA, Grunberger G, Anhalt H, et.al. Continuous glucose monitoring: A consensus conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocrine Practice*. 2016; 22(8):1008-1021. Available from: <https://journals.aace.com/doi/pdf/10.4158/EP161392.CS>. Accessed December 9, 2022.
13. Heller SR. International Hypoglycaemia Study Group (IHSG): Glucose concentrations of less than 3.0 mmol/L (54 mg/dL) should be reported in clinical trials: a joint position statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2017;40:155–157. Available from <https://care.diabetesjournals.org/content/40/1/155>.
14. DeSalvo DJ, Miller KM, Hermann JM, et al. Continuous glucose monitoring and glycemic control among youth with type 1 diabetes: International comparison from the T1D Exchange and DPV Initiative. *Pediatr Diabetes*. 2018;19:1271–1275. 10.1111/pedi.12711

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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