

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
Dexcom Product Line	Preferred
Freestyle Libre Product Line 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 • Simplera (system/kit, sensors) 	Non-Preferred

Product/Product Line	Quantity Limit
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
Dexcom G7 15 day Sensor	2 sensors per 30 days

Freestyle Libre reader*	1 reader per year (based on manufacturer warranty)
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 2 Plus Sensor	2 sensors per 30 days
Freestyle Libre 3 Reader*	1 reader per year
Freestyle Libre 3 Sensor	2 sensors per 28 days
Freestyle Libre 3 Plus Sensor	2 sensors per 30 days
Guardian Real-Time Replacement Receiver/Monitor*	1 receiver per year
Guardian Connect Transmitter*	2 transmitters per year
Guardian Link 3 Transmitter*	1 transmitter per year
Guardian Sensor (3)	5 sensors per 30 days
Guardian 4 Transmitter*	1 transmitter per year
Guardian Sensor (4)	5 sensors per 30 days
Enlite Sensor	5 sensors per 30 days
Eversense E3 Transmitter*	1 transmitter per year
Eversense E3 Sensor	2 sensors per year
Eversense 365 Smart Transmitter*	1 transmitter per year
Eversense 365 Sensor	1 sensor per year
Simplera system/kit	1 system/kit (5 sensors) per 30 days; one time fill
Simplera sensor	5 sensors per 30 days
Simplera Sync sensor	5 sensors per 30 days

APPROVAL CRITERIA

Step Therapy for non-preferred agents

All states except for CA IND - Requests for non-preferred continuous glucose monitoring (CGM) devices and CGM supplies (receiver, transmitter, sensor) must meet the following criteria:

- I. Documentation is provided that individual has had a trial and inadequate response or intolerance to the preferred continuous glucose monitor (Dexcom Product Line); **OR**
- II. Documentation is provided that individual utilized an insulin pump that is only compatible with a non-preferred continuous glucose monitor.

CA IND – Step Therapy does not apply (Dexcom Product Line is non-formulary)

Prior Authorization for all agents

Initial requests for *personal long-term use* of non-implanted and implanted continuous glucose monitoring device (CGM) and CGM supplies may be approved if the following criteria are met:

- I. Individual has been diagnosed with diabetes mellitus (any type); **AND**
- II. Insulin injections are required multiple times daily or an insulin pump is used for maintenance of blood sugar control; **AND**,
- III. Individual or caregiver(s) demonstrates the following:
 - A. An understanding of the technology, including but not limited to the use of the device to recognize alerts and alarms; **AND**
 - B. Motivation to use the device correctly and consistently; **AND**
 - C. Continued participation in a comprehensive diabetes treatment plan; **AND**
- IV. Any of the following are present despite ongoing management using self-monitoring and insulin administration regimens to optimize care:
 - A. Inadequate glycemic control, demonstrated by HbA1c measurements above target; **OR**
 - B. Persistent fasting hyperglycemia; **OR**
 - C. Recurring episodes of hypoglycemia (blood glucose <50 mg/dL); **OR**
 - D. Hypoglycemia unawareness that puts the individual or others at risk; **OR**
 - E. In children and adolescents with type 1 diabetes who have achieved HbA1c levels below 7%, when treatment is intended to maintain target HbA1c levels and limit the risk of hypoglycemia;

AND

- V. If requesting an implantable CGM (Eversense), individual must be 18 years of age or older.

Continuation requests for non-implanted and implanted continuous glucose monitoring devices (CGM) and 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. The CGM device has resulted in desired clinical benefit (including but not limited to HbA1c control or fewer episodes of symptomatic hypoglycemia or hyperglycemia).

Quantity Override:

The *replacement* of non-implanted 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.

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

- I. Individual met the initiation criteria at the time of the first request for the CGM device.

Use of personal non-implanted and implanted continuous glucose monitoring devices (CGM) and CGM supplies may not be approved when the above criteria are not met and for all other indications.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
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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.
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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
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20. Freestyle Libre 3 User Guide: Available from: https://freestyleserver.com/Payloads/IFU/2022/ART44255-001_rev-A-Web.pdf. Accessed December 9, 2022.

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