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: • Enlite sensors • Guardian (monitors, receivers, sensors, transmitters) • Minimed Guardian sensor • Sof-sensor ^Step Therapy Does not apply in California	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 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 Reader*	1 reader per year
Freestyle Libre 3 Sensor	2 sensors per 28 days
Guardian Connect Transmitter*	2 transmitters 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
Eversense Smart Transmitter*	1 transmitter per year

APPROVAL CRITERIA

Step Therapy for non-preferred agents

All states except for CA - Requests for non-preferred continuous glucose monitoring (CGM) devices and CGM 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 to the preferred continuous glucose monitor (Dexcom Product Line); **OR**
II. Individual utilized an insulin pump that is only compatible with a non-preferred continuous glucose monitor.

CA – Step Therapy does not apply

Prior Authorization for all agents

Initial requests for p*ersonal 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. Individual has inadequate glycemic control despite multiple alterations in self-monitoring and insulin administration regimens to optimize care; **AND**
V. Any of the following are present despite multiple alterations in 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 mL/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

VI. 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); **AND,**
III. Individual has used the device as intended.

<u>*Quantity Override:</u>

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 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.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; 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.
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8. ElSayed NA, Aleppo G, Aroda VR, et al. 7. Diabetes Technology: Standards of Care in Diabetes-2023. Diabetes Care. 2023;46(Suppl 1):S111-S127. doi:10.2337/dc23-S007.
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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.
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15. Guardian Connect User Guide. Available from: https://www.medtronicdiabetes.com/sites/default/files/library/download-library/user-guides/GuardianT%20Connect%20CGM%20System%20User%20Guide.PDF. Accessed December 9, 2022.
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17. Dexcom G5 User Guide. Available from: https://s3-us-west-2.amazonaws.com/dexcompdf/G5-Mobile-Getting-Started-Guide-Touchscreen-Receiver.pdf. Accessed December 9, 2022.
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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.

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