

**Continuing Blood Glucose Monitors (CGM)
 Dexcom 6
 FreeStyle Libre Products
 Effective 01/01/2023**

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Continuous glucose monitors (CGM) are minimally invasive or noninvasive devices that measure glucose levels at set intervals, 24 hours a day, with a small electrode placed under the skin and held in place by an adhesive. Glucose measurements are recorded and translated into real time data, generating glucose direction and rate of change.

Products not covered through pharmacy*	Products that require PA*
Dexcom G4	Dexcom G6 [®]
Dexcom G5	Freestyle Libre products
Enlite	
Eversense	
Freestyle Navigator	
Guardian	

*These products are not available through the pharmacy benefit; however, may be covered under Durable Medical Equipment (DME) with a PA.

The following NDCs are included will reject at the pharmacy as prior authorization required. Any NDC that is not listed here is not included will reject at the pharmacy level with Exception Code 4114 (Product/service not covered, Plan/Benefit Exclusion).

Dexcom G6[®]

08627-0091-11 Dexcom G6 Receiver Kit (GSN 065863)

08627-0016-01 Dexcom G6 Transmitter Kit (GSN 065873)
08627-0053-03 Dexcom G6 Sensor 3-pack (GSN 065744)

Freestyle Libre 14 day[®] and Freestyle Libre 2[®]

57599-0002-00 FreeStyle Reader Kit 14 Day (GSN 077832)*
57599-0001-01 FreeStyle Sensor Kit 14 Day (GSN 077828)*
57599-0803-00 FreeStyle 2 Reader (GSN 077832)
57599-0800-00 FreeStyle 2 Sensor (GSN 077828)

*NDC is included in the manufacturer contract; however, product is obsolete

Coverage Guidelines

Approval of a Dexcom 6 and FreeStyle Libre system may be granted for members who meet the following criteria and documentation is submitted:

1. Member has a diagnosis of diabetes mellitus (see Appendix for off-label indications)
2. Member has a paid claim or physician attestation requiring multiple daily insulin administrations or an insulin pump†
3. ONE of the following is met:
 - a. A1c \geq 7% or value that does not meet documented target treatment goal
 - b. Frequent hypoglycemia (or nocturnal hypoglycemia)
 - c. History of hypoglycemic unawareness
 - d. Dawn phenomenon with fasting blood sugars frequently exceeding 200 mg/dL.
 - e. History of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia
 - f. Use with compatible insulin pump to achieve glycemic control
 - g. Pregnancy

† Members not receiving insulin due to physical disability, visual impairment, cognitive impairment, or age <18 years may bypass this requirement.

Continuation of Therapy

Reauthorization may be granted with current documentation from the prescriber when the following criteria are met:

1. Prescriber documents improvement in diabetic control/relative stability (e.g., provider attestation or A1c improvement can be considered to meet this requirement)
2. Provider attestation that the member’s CGM data has been reviewed and is being used to monitor or adjust treatment plan

Limitations

1. Initial requests and reauthorizations will be authorized for 12 months.
2. The following quantity limits apply:

Monitor	1 monitor per year
Receiver	1 receiver per year
Transmitter	1 transmitter per 90 days
Sensor	3 sensors per month

Appendix

Appendix: Off-Label requests for CGM

Continuous glucose monitoring devices are only FDA-approved for patients with a diagnosis of diabetes mellitus. However, there are other populations that may benefit from glucose monitoring and therefore, may be appropriate candidates for CGM. Members with another non-diabetes based condition causing a disorder of



glucose metabolism of improper endogenous insulin secretion resulting in frequent hypoglycemia, nocturnal hypoglycemia, or hypoglycemic unawareness may require blood glucose monitoring. Examples of these disorders include but are not limited to:

- Seizure disorder
- Insulinoma
- Genetic conditions causing hyperinsulinemia
- Effect from post-surgical conditions (i.e., post esophagectomy, post fundoplication, post gastrectomy, post gastric bypass, post sleeve gastrectomy)

For these members, requests should document hypoglycemic risk and past events and should provide rationale for use of CGM instead of capillary blood glucose monitoring using test strips and a blood glucose meter.

Examples of rationale for use of CGM instead of capillary blood glucose monitoring include but are not limited to:

- Frequent hypoglycemia,
- Nocturnal hypoglycemia,
- History of hypoglycemic unawareness,
- Limited dexterity, and
- Comorbid conditions that would impact ability to prick fingers (e.g., Raynaud's, autism, etc.)

Exclusions

1. Replacement or repair of home long-term (more than 7 days) continuous glucose monitors when
 - a. It is still under manufacture warranty.
 - b. It is lost, stolen, or damaged due to improper care, or misuse, or neglect (the plan may require proof of the stolen or damaged item. Proof consists of a police report, pictures, or corroborating statement).
 - c. The member has a functioning model and a newer or upgraded model is not medically necessary.
2. Devices or device features that are to be principally used for convenience and are not medically necessary.

References

1. Kudva YC, Ahmann AJ, Bergenstal RM, et al. Approach to Using Trend Arrows in the FreeStyle Libre Flash Glucose Monitoring Systems in Adults. *J Endocr Soc* 2018; 2:1320
2. American Diabetes Association. 7. Diabetes Technology: Standards of Medical Care in Diabetes-2019. *Diabetes Care* 2019; 42:S71
3. Welsh JB, Gao P, Derdzinski M, et al. Accuracy, Utilization, and Effectiveness Comparisons of Different Continuous Glucose Monitoring Systems. *Diabetes Technol Ther* 2019; 21:128

Review History

11/20/2019 – Reviewed at P&T

11/19/2020 – Updated and Reviewed Nov P&T; Added Freestyle Libre 2 to criteria

05/19/2021 – Updated and Reviewed May P&T; removed Type 1 diabetes and replaced with diabetes mellitus; Added reauthorization approval length; added QL; updated coverage guidelines and reauthorization guidelines. Effective 6/1/21.

09/01/2021 – Updated QL for transmitter. Effective 9/1/21.

09/22/2021 – Reviewed at P&T

11/17/2021 – Reviewed and Updated for Nov P&T: Guideline updated to add six new agents to UPPL including: Dexcom G4, Dexcom G5, Enlite, Eversense, Freestyle Navigator, and Guardian. Guideline updated to reflect preferred agents with “PD”. Additionally, the criteria were updated to remove blood glucose testing



requirement and wording of the insulin requirement was updated from multiple daily insulin injections to multiple daily insulin administrations. Criteria for A1c not meeting goal was updated to remove requirement of education and adherence to blood glucose testing. Effective 01/01/2022

03/16/2022 – Reviewed and Updated for March P&T; Guideline updated to include appendix for guidance for off-label requests. Additionally, NDCs 57599-0000-21 and 57599-0000-19 for Freestyle Libre 10 are obsolete, therefore a footnote was added for clarification. Effective 05/01/2022

11/16/2022 – Reviewed and Updated for Sept P&T; separated out MH vs. Comm/Exch. Changed Freestyle Libre 14 and Freestyle Libre 2 to Freestyle Libre products to allow for any new Freestyle Libre CGM on the market. Effective 01/01/2023.

