Continuous Glucose Monitoring (FreeStyle Libre®, Dexcom G6®) EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO107

Description

Continuous glucose monitoring (FreeStyle Libre, Dexcom G6) is a system used to measure blood sugar throughout the day and overnight in type 1 diabetes mellitus (T1DM) patients.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
Continuous glucose monitoring (FreeStyle Libre, FreeStyle Libre 2)	14-day sensors	Type 1 diabetes mellitus	2 sensors/28 days
	Reader/meter		1 meter/1 year*
Continuous glucose monitoring (Dexcom G6)	Sensor	Type 1 diabetes mellitus	3 sensors/30 days
	Transmitter		4 transmitters/365 days
	Reader/meter		1 meter/1 year*

*Meter is under manufacturer warranty for first year

Initial Evaluation

I. Real-time continuous glucose monitoring (Freestyle Libre, Dexcom G6) may be considered medically necessary when the following criteria below are met:
   A. Member has a diagnosis of T1DM within the following population groups:
      1. Member is 21 years of age or older; **AND**
         i. Meets <u>one</u> of the following insulin management therapies:
            a. Member is on insulin pump management; **OR**
            b. Member is NOT on insulin pump management with <u>one</u> of the following signs or symptoms prior to initiation of continuous glucose monitoring:
               i. HbA1c ≥8.0%
               ii. Frequent or severe hypoglycemia
               iii. Impaired awareness of hypoglycemia; **AND**
         ii. Member has received diabetes education specific to the use of continuous glucose monitoring; **OR**

2. Member is <21 years of age; **AND**
    i. Member has received diabetes education specific to the use of continuous glucose monitoring; **OR**
3. Member is pregnant or plans to become pregnant within six months; **OR**
4. Member has a documented necessity for the use of continuous glucose monitoring; **AND**
    i. Documentation of medical necessity has been provided.

II. Real-time continuous glucose monitoring (Freestyle Libre, Dexcom G6) is considered not medically necessary when criteria above are not met and/or when used for
    A. Any condition other than type 1 diabetes mellitus

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent; **AND**
II. Member has used the device for at least 50% of the time at their first follow-up visit; **AND**
III. Member experienced a positive clinical response (e.g., decrease in HbA1c, decrease hypoglycemia frequency).

Supporting Evidence

I. A high-quality systematic review of adults with T1DM showed that there is low-quality evidence of no difference with CGM versus controls in severe hypoglycemia (7.9% vs 7.5% [95% CI 0.63, 1.77]), ketoacidosis (2% vs 2.3% [95% CI 0.32, 2.26]), or quality of life at six months.
    - There is moderate-quality evidence that CGM reduces HbA1c more than control at 6 months (mean difference -0.2% [95% CI -0.1%, -0.4%])
II. A second high-quality systematic review showed that there were greater HbA1c reductions for participants over the age of 15 using CGM as compared to control groups (-0.356% [95% CI -0.551%, -0.160%, p<0.001]).
III. Though there is little evidence for clinical benefit, the Health Evidence Review Commission (HERC) Coverage Guidance makes a weak recommendation for the use of CGM in children and adolescents with T1DM based off parental satisfaction and long-term developmental concerns.
IV. There is insufficient evidence regarding CGM on long-term clinical outcomes (e.g. HbA1c reduction, ketoacidosis, hypoglycemia, etc.) for use of CGM in adults or children with type 2 diabetes mellitus.
V. HERC recommends coverage in adults with type 1 diabetes who have used the device for at least 50% of the time at their first follow-up visit.

Investigational or Not Medically Necessary Uses

I. According to the Oregon Health Authority (OHA) Health Evidence Review Commission (HERC), real-time CGM is not recommended for coverage in adults with type 2 diabetes. CGM is not recommended for coverage during pregnancy for type 2 diabetes or gestational diabetes. HERC found insufficient evidence regarding the effects of CGM on long-term clinical outcomes or on severe hypoglycemia in type 2 diabetes. HERC has low confidence that improvements in HbA1c levels seen in type 2 diabetes studies are clinically significant.

References

1. Langendam, M., Luijf, Y. M., Hooft, L., Devries, J. H., Mudde, A. H., & Scholten, R. J. (2012). Continuous glucose monitoring systems for type 1 diabetes mellitus. The Cochrane Database of Systematic Reviews, 1, Cd008101. DOI: 10.1002/14651858.CD008101.pub2
2. Benkhadra, K., Alahdab, F., Tamhane, S., Wang, Z., Prokop, L. J., Hirsch, I. B., ... Murad, M. H. (2016). Real time continuous glucose monitoring in type 1 diabetes: A systematic review and individual patient data meta-analysis. Clinical Endocrinology. DOI: 10.1111/cen.1329.
3. Health Evidence Review Commission. (2017). Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus. Retrieved from https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-CGM-DM-2017.pdf

Policy Implementation/Update:

Date Created	September 2017
Date Effective	October 2017
Last Updated	October 2019
Last Reviewed	10/2018, 10/2018

Action and Summary of Changes	Date
Updated QL table to include 14-day sensor wording along with updated QL for the 14-day sensors as the 10-day sensor was discontinued. Also updated to include Freestyle Libre 2	09/2020
Criteria transitioned into policy format with supporting evidence and not medically necessary sections included	10/2019
Criteria created	09/2018