# Continuous Glucose Monitoring Systems
## EOCCO POLICY

## Policy Type: PA  Pharmacy Coverage Policy: EOCCO107

### Description
Real-time continuous glucose monitoring (CGM) is a system used to measure blood sugar throughout the day and overnight in type 1 diabetes mellitus (T1DM), type 2 diabetes mellitus (T2DM) and gestational diabetes patients.

### Length of Authorization
- Initial: 12 months
- Renewal: 12 months

### Quantity limits

| Product Name | Indication | Dosage Form | Quantity Limit |
|---|---|---|---|
| Dexcom G6 | Diabetes Mellitus | System meter | 1 meter per 365 days |
| | | Transmitter | 1 transmitter per 90 days |
| | | Sensors | 3 sensors (1 kit) per 30 days |
| Dexcom G7 | | System meter | 1 meter per 365 days |
| | | Sensors | 3 sensors (1 kit) per 30 days |
| Freestyle Libre | | Reader | 1 reader per 365 days |
| | | Sensor (14 day) | 2 sensors per 28 days |
| Freestyle Libre 3-Plus Sensor | | Sensor (15 day) | 2 sensors per 30 days |
| Medtronic Guardian CGM | | Transmitter | 1 transmitter per 365 days |
| | | Sensor | 5 sensors per 30 days |
| Eversense CGM system | | Transmitter | 1 transmitter per 365 days |
| | | Sensor | 1 sensor per 90 days |

### Initial Evaluation
I. **Dexcom** and **Freestyle Libre CGM products** may be considered medically necessary when the following criteria 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.; **OR**

B. Member has a diagnosis of T2DM or gestational diabetes or diabetes due to underlying conditions or chemical induced diabetes; **AND**
1. Member is currently using insulin therapy; **AND**
2. Member has received diabetes education specific to the use of continuous glucose monitoring; **AND**
3. Meets <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
    iv. Documentation of diabetes-related complications (i.e. peripheral neuropathy, end-organ damage).

II. **All other CGM products (e.g. Medtronic, Eversense, etc.)** may be considered medically necessary when the following criteria below are met:
A. Criteria I(A.1)-(B.2) are met; **AND**
B. Use of Dexcom AND Freestyle Libre products have been ineffective, not tolerated, or not indicated; **OR**
C. Member uses an insulin pump not compatible with preferred Dexcom or Freestyle Libre CGM products (e.g Medtronic MiniMed).

III. Real time continuous glucose monitoring (CGM) is considered <u>not medically necessary</u> when criteria above are not met and /or when used for:
A. Type 2 diabetes mellitus or gestational diabetes or diabetes due to underlying conditions or chemical induced diabetes who **do not** require insulin therapy

**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 has a diagnosis of:
- T1DM (Type 1 Diabetes Mellitus); **OR**
- T2DM (Type 2 Diabetes Mellitus); **OR**
- Diabetes due to underlying conditions or chemical induced diabetes; **OR**
- Gestational Diabetes; **AND**

IV. 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. HERC recommends coverage in adults with type 1, type 2 and gestational diabetes who have used the device for at least 50% of the time at their first follow-up visit.

V. As of September 2023, Oregon Health Authority (OHA) HERC has provided new guidance and coverage allowance for use of CGM in adults or children with type 2 diabetes mellitus or gestational diabetes who are requiring insulin therapy.

VI. A HERC review conducted of RCTs and other publications in adults and children with T2DM showed that there is very low-quality evidence with no statistical significance for CGM versus self-monitoring of blood glucose (SMBG) in reporting severe hypoglycemic events. It was found that the reported severe hypoglycemic events were not associated with use of a CGM.

VII. A HERC review conducted of RCTs and other publications of adults with T2DM showed that there is low-quality evidence that CGM versus SMBG provided a reduction in HbA1c (i.e. ≥0.5%) but not found statistically significant (MD, −0.23%; 95% CI, −0.49 to 0.03; P = .09) at 24 weeks or later. However, the benefits of monitoring and some level of HbA1c reduction outweigh the low-quality and risks.

VIII. There is little evidence for clinical benefit and low-quality evidence in use of CGM of perinatal individuals with T2DM. It was a small sample size and underpowered to detect differences between groups; however, the benefits outweigh the risk in this higher risk pregnancy

populations to optimize blood glucose control and potentially reduce complications associated with diabetes in both maternal and neonatal individuals.

IX. At this time, HERC does not recommend coverage of CGM in individuals who do not use insulin therapy. There is a lack of evidence to demonstrate meaningful clinical outcomes in these individuals and the ability to demonstrate that the benefits would outweigh the risks.

## 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 individuals with type 2 diabetes or gestational diabetes who do not use insulin therapy. HERC found insufficient evidence regarding the effects of CGM on long-term, clinically meaningful outcomes or on severe hypoglycemia in type 2 diabetes or gestational diabetes without the use of concurrent insulin therapy. HERC found no eligible studies that evaluated the effectiveness of CGM for children, adolescents, or pregnant individuals with gestational diabetes without insulin therapy .

## References

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3. Health Evidence Review Commission. (2023). Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus. Retrieved from https://www.oregon.gov/oha/HPA/DSI-HERC/EvidenceBasedReports/CG-CGM-DM-2017.pdf
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5. MiniMed 630G System Support. Medtronic website. https://www.medtronicdiabetes.com/customer-support/minimed-630g-system-support/linking-your-pump-to-a-meter.
6. Minimed 770G System. Medtronic website. https://www.medtronicdiabetes.com/products/minimed-770g-insulin-pump-system.
7. Eversense CGM system website. https://www.eversensediabetes.com/
8. Dexcom G7 system. Dexcom website. https://www.dexcom.com/en-us/g7-cgm-system

## Policy Implementation/Update:

| Action and Summary of Changes | Date |
|---|---|
| Reworded of criteria to incorporate other types of diabetes | 01/2025 |
| Added Freestyle Libre 3 plus sensor | 06/2024 |
| Effective 01/01/2024: Added criteria and supportive evidence for expanded coverage in use of type 2 diabetes mellitus and gestational diabetes individuals who are on insulin therapy | 12/2023 |
| Update to Medtronic sensor QL from 5 sensors in 35 days to 5/30 | 10/2023 |
| Added Medtronic Guardian 4 to the policy | 06/2023 |
| Effective 04/01/2023: Added Dexcom G7 CGM system to policy. Updated to include additional CGMs. | 04/2023 |