PRIOR AUTHORIZATION CRITERIA

CONTINUOUS GLUCOSE MONITORS

BRAND NAME*
(generic)

DEXCOM (ALL PRODUCTS)

EVERSENSE (ALL PRODUCTS)

FREESTYLE LIBRE (ALL PRODUCTS)

GUARDIAN (ALL PRODUCTS)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 3888-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

COVERAGE CRITERIA

The requested continuous glucose monitor will be covered with prior authorization when the following criteria are met:

- The patient has a diagnosis of diabetes mellitus
  AND
  - The patient is using an intensive insulin regimen [Note: An intensive insulin regimen is defined as multiple daily injections (i.e., 3 or more injections per day) or insulin pump therapy]
    AND
    - The request is for a continuation of therapy and the patient has experienced improved glycemic control or decreased hypoglycemia episodes while using a continuous glucose monitor (CGM)

    OR
    - The request is for a continuation of therapy and the patient is being assessed every six months by the prescriber for adherence to their continuous glucose monitor (CGM) regimen and diabetes treatment plan

    OR
    - The patient is less than 18 years of age

    OR
    - The patient is not meeting glycemic targets OR the patient is experiencing hypoglycemia (including hypoglycemia unawareness)

OR

- The patient has a diagnosis of glycogen storage disease

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines.

Continuous Glucose Monitors (CGMs) are devices that measure interstitial glucose (which correlates well with plasma glucose). CGMs monitor glucose levels continuously and either provide the user with automated alarms and alerts at specific glucose levels (real-time CGM) or only display glucose values when swiped by a reader or a smart phone that reveals the glucose levels (intermittently scanned CGM).[1] CGM use facilitates modest improvements in glucose control as

measured by A1c without increasing, and sometimes decreasing, the risk of hypoglycemia, thus facilitating safer intensification of glucose control.[2] According to a joint consensus statement by the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE), use of real-time CGM on a frequent basis in children and adults with type 1 diabetes (T1DM) is strongly supported by evidence from several randomized, controlled trials (RCTs).[2] An international consensus on use of continuous glucose monitoring also recommends that CGM be considered in patients with T2DM who are using intensive insulin therapy who are not achieving glucose targets, especially if the patient is experiencing problematic hypoglycemia.[3] Intensive insulin therapy is defined as multiple daily injections (MDI) or continuous subcutaneous administration through an insulin pump.[1] The American Diabetes Association (ADA) guidelines for diabetes care support use of CGMs in conjunction with multiple daily injections and continuous subcutaneous insulin infusions and other forms of insulin therapy as a tool to lower and/or maintain A1c levels and/or reduce hypoglycemia in adults and youth with diabetes. Patients less than 18 years of age with diabetes mellitus who are using an intensive insulin regimen will be considered for approval. For patients 18 years of age or older with diabetes mellitus using an intensive insulin regimen, coverage will be considered if the patient is not meeting glycemic targets or is experiencing hypoglycemia (including hypoglycemia awareness).

For patients who are continuing therapy with a continuous glucose monitor, coverage will be considered if the patient has experienced improved glycemic control or decreased hypoglycemia episodes while using a continuous glucose monitor (CGM). If the patient is not currently experiencing improvement while using their CGM, coverage will be considered if the patient is being assessed by the prescriber every six months for adherence to their CGM regimen and diabetes treatment plan.[4]

In addition to patients with diabetes, patients with glycogen storage disease (GSD) can also benefit from use of a continuous glucose monitor (CGM). GSD is a rare disease in which the primary concern of the disease is hypoglycemia. Symptoms of GSDI usually begin at three to four months of age and include enlargement of the liver (hepatomegaly), kidney (nephromegaly), elevated levels of lactate, uric acid and lipids (both total lipids and triglycerides), and possible seizures caused due to repeated episodes of hypoglycemia. Continued low blood sugar can lead to delayed growth and development and muscle weakness.[9] A 2018 study found glycogen storage disorder (GSD) patients spent 4–8% of their time in hypoglycemia. Of concern is the fact that patients were unaware of these asymptomatic episodes which may have remained unrecognized by self-monitoring blood glucose (fingerstick) monitoring alone. The prevalence of subclinical hypoglycemia in this cohort whose care is managed in a tertiary care center with good oversight shows that even with heightened vigilance and an abundance of caution, dangerous blood glucose lows can occur in liver GSD patients, which may be missed by self-monitoring blood glucose alone.[6] Additionally a 2019 review of glycemic control and complications in glycogen storage disease type I (GSDI) concluded that the quality of glucose control is related to the presence of typical long-term complications in GSDI. Many patients experience episodes of asymptomatic low blood glucose. Regular assessment of glucose control is an essential element to evaluate the quality of treatment, and increasing the frequency of glucose self-monitoring remains an important goal of patient education and motivation. CGM devices may support patients to optimize dietary therapy in everyday life.[5] A 2011 analysis of the use of continuous glucose monitoring in the practical management of glycogen storage disorders showed that the use of CGM, combined as appropriate with lactate and / or ketone measurements, and subsequent management changes have led to improved biochemical control. They recommend use of continuous glucose monitoring together with other appropriate home monitoring (lactate, ketones) and other regular investigations including biochemical and hematological indices, liver ultrasound scans and careful assessment of growth parameters as it avoids hospital admissions and associated repeated venepuncture.[7] A 2014 analysis of CGM in children with glycogen storage disease type I found that continuous glucose monitoring was associated with reduced time spent in hypoglycemia and a concomitant decrease in liver size by clinical examination, lactate, aspartate aminotransferase, alanine aminotransferase and triglyceride concentrations in children with GSDI.[8] Coverage will be considered for patients with a diagnosis of glycogen storage disease.

REFERENCES

1. American Diabetes Association. Standards of Medical Care in Diabetes-2021: *Diabetes Care* January 2021;44(Supplement1).
2. Fonseca VA, Grunberg G, Anhalt H et al. Continuous glucose monitoring: a consensus conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. *Endocr Pract* 2016;22(No. 8):1008-1021.

3. Danne T, Nimri R, Battelino T et al. International Consensus on use of Continuous Glucose Monitoring. *Diabetes Care* 2017;40:1631-1640.
4. Local Coverage Determination (LCD) for Glucose Monitors (L33882); Revision Effective Date 07/18/2021; https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?articleId=52464&LCDId=33822&NCAId=231&NCDId=5&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=Ed%7CKey%7CSAD%7CFAQ&PolicyType=Final&s=%26mdash%3B-%7C5%7C6%7C66%7C67%7C9%7C38%7C63%7C41%7C64%7C65%7C44&KeyWord=continuous+glucose+monitoring&KeyWordLookUp=Doc&KeyWordSearchType=And&kq=true&bc=IAAAABgAAAAAAAAA&. Accessed August 23, 2021.
5. Kaiser N, Gautschi M, Bosanka L, et al. Glycemic control and complications in glycogen storage disease type I: Results from the Swiss registry. *Molecular Genetics and Metabolism* 2019; 126 (4): 355-361.
6. Herbert M, Pendyal S, Rairkar M, et al. Role of continuous glucose monitoring in the management of glycogen storage disorders. *Journal of Inherited Metabolic Disease* 2018; 41: 917-927.
7. White F, Jones S. The use of continuous glucose monitoring in the practical management of glycogen storage disorders. *Journal of Inherited Metabolic Disease* 2011; 34: 631-642.
8. Kasapkara C, Demir G, Hasanoglu A. Continuous glucose monitoring in children with glycogen storage disease type I. *European Journal of Clinical Nutrition* 2014; 68: 101-105.
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CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of diabetes mellitus? [If no, then skip to question 8.]	Yes	No
2	Is the patient using an intensive insulin regimen? [Note: An intensive insulin regimen is defined as multiple daily injections of insulin (i.e., 3 or more injections per day) or insulin pump therapy.] [If no, then no further questions.]	Yes	No
3	Is this a request for continuation of therapy with a continuous glucose monitor (CGM)? [If no, then skip to question 6.]	Yes	No
4	Has the patient experienced improved glycemic control or decreased hypoglycemia episodes while using a continuous glucose monitor (CGM)? [If yes, then no further questions.]	Yes	No
5	Is the patient being assessed every six months by the prescriber for adherence to their continuous glucose monitor (CGM) regimen and diabetes treatment plan? [No further questions.]	Yes	No
6	Is the patient 18 years of age or older? [If no, then no further questions.]	Yes	No

7	Is the patient currently not meeting glycemic targets OR is the patient experiencing hypoglycemia (including hypoglycemia unawareness)? [No further questions]	Yes	No
8	Does the patient have a diagnosis of glycogen storage disease?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Go to 2	Go to 8	
2.	Go to 3	Deny	You do not meet the requirements of your plan. Your plan covers a continuous glucose monitor when you are using an intensive insulin regimen. Your request has been denied based on the information we have. [Short Description: No intensive insulin regimen]
3.	Go to 4	Go to 6	
4.	Approve, 12 months	Go to 5	
5.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers a continuous glucose monitor when you meet one of the following conditions: - You need to continue using a continuous glucose monitor and you have experienced improved glycemic control or decreased hypoglycemia with your continuous glucose monitor - You need to continue using a continuous glucose monitor and your prescriber sees you every six months to make sure you follow your continuous glucose monitor regimen and diabetes treatment plan Your request has been denied based on the information we have. [Short Description: Continuation of therapy, no improvement or prescriber monitoring]
6.	Go to 7	Approve, 12 months	
7.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers a continuous glucose monitor when you meet one of the following conditions: - You are less than 18 years of age - You cannot meet your diabetes goals - You have low blood sugar Your request has been denied based on the information we have. [Short Description: Does not meet the following: less than 18 years of age, glycemic targets not met or hypoglycemia]
8.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers a continuous glucose monitor when you have one of the following diagnosis: - diabetes mellitus. - glycogen storage disease Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]