Continuous Glucose Monitoring Systems

A Continuous Glucose Monitor (CGM) is an FDA-approved medical device that records glucose levels throughout the day and night utilizing an appropriate sensor. The sensor must be able to determine tissue glucose levels at predetermined intervals and transmit the information to a device capable of retaining the data and providing the patient with the needed information. CGMs are considered medically necessary for insulin-dependent individuals with poorly controlled blood sugar. For the purposes of these guidelines, "poorly controlled" blood sugar level is defined as unexplained hypoglycemic episodes, hypoglycemic unawareness, suspected post-prandial hyperglycemia, or recurrent diabetic ketoacidosis.

Continuous Glucose Monitors and all related supplies are covered under the Durable Medical Equipment (DME) benefit. Prior Authorization is required and approval is valid for a maximum of 12 months.

Coverage Criteria

1. INITIAL coverage will be considered medically necessary for individuals who meet the following criteria:

a) The member has a diagnosis of insulin-dependent diabetes; AND

b) The member requires multiple daily insulin administrations, or an insulin pump is being used. (*Exceptions: Providers may request an exception from the insulin use requirement for individuals not receiving insulin due to physical disability, visual impairment, cognitive impairment, or age <18; and such instances may bypass this requirement. Other comorbidities will be reviewed on a case-by-case basis.);* AND

c) The member meets at least one of the following:

i. HbA1c ≥7% or at a value that does not meet documented target treatment; OR

ii. Frequent hypoglycemia or nocturnal hypoglycemia; OR

iii. History of hypoglycemic unawareness; OR

iv. Dawn phenomenon with fasting blood sugars frequently exceeding 200mg/dL; OR

v. History of emergency room visit or hospitalization related to ketoacidosis or hypoglycemia; OR

vi. Use of a compatible insulin pump to achieve glycemic control; OR

vii. Pregnancy.

OR

d) The member has another non-diabetes-based condition causing disorder of glucose metabolism or improper endogenous insulin secretion resulting in frequent hypoglycemia or nocturnal hypoglycemia or hypoglycemic unawareness. Such disorders may include, but are not limited to, seizure disorder, insulinoma, genetic conditions causing hyperinsulinemia, effects from post-surgical conditions including post esophagectomy, post fundoplication, post gastrectomy, post gastric bypass, and post sleeve gastrectomy. Such cases should speak to hypoglycemic risk and events and will be reviewed on a case-by-case basis.

2. CONTINUED USE is considered medically necessary in each of the following circumstances:

a) There is objective documented evidence of improvement in control of diabetes (specific to baseline status of disease for individual members); OR

b) There is documented evidence of compliance with a current CGM treatment plan based on log data of the device; OR

c) If a member is new to RI Medicaid from another insurer and is stable on CGM.

Replacement

The replacement of a CGM system is considered reasonable and medically necessary when ALL the following indications are met:

1. Supporting documentation is in the form of clinical notes or letters generated by a clinician overseeing the member's diabetic condition; AND

2. The present monitor has been rendered ineffective or inoperable due to EITHER:

a. A change in condition that the current monitor is unable to accommodate; OR

b. Damage by events outside the control of the user;

AND

3. The device has been used according to a current treatment plan; AND

4. Continued use of the device is clinically supported; AND

5. Device replacement cannot be obtained from the manufacturer or supplier for reasons including the expiration of device warranty; AND

6. Loss/damage is not attributable to abuse, damage, or neglect on the part of the user; AND

7. The cost of replacement rather than repair is justified by the nature of the damage and the useful lifetime of the device; AND

8. Replacement is not an additional/backup monitor; AND

9. Replacement monitor is synonymous to the monitor being replaced unless replacement has been necessitated by a change in member condition that the old device is unable to accommodate.

Note: in cases where neither the make and model of the device being replaced nor directly competitive devices from other brands are available, approval of a new device will be based on meeting the Coverage Criteria set forth above.

Non-coverage

Continuous glucose monitors are not considered medically necessary under certain circumstances where effectiveness has not been established or when there is non-compliance or an inability to comply with a current treatment plan. Examples of such circumstances include, but are not limited to, the following:

1. Non-FDA-approved devices.

2. Remote continuous glucose monitoring devices, accessories, and additional hardware or software that are ancillary to CGMs and are not considered medically necessary (e.g., complementary watches.)

3. Replacement of an existing CGM with another CGM for additional features which are not medically necessary.

4. CGMs are contraindicated for individuals who are unable or unwilling to perform required necessary calibration of a CGM, which may include, but not be limited to, self-monitored blood

glucose checks at least twice per day; or when a member's symptoms and clinical presentation do not match/align with device readings, or for members who do not maintain contact with their health care professionals.

Submitting Clinical Documentation

Requests for PA for continuous glucose monitors must be accompanied by clinical documentation that supports the medical necessity of the requested device. Clinical documentation by the provider of the supporting rationale for the requested device must show that the member's blood sugar remains poorly controlled despite appropriate adjustments to a physician-ordered and physician-monitored treatment plan based on previous self-monitoring. Specifically, documentation of medical necessity must include ALL the following:

1. Documentation that indicates that the member remains compliant with the insulin therapy recommended by an endocrinologist for at least 3 months. Exceptions: Providers may request and exception to the compliance requirement due to co-morbidities that inhibit the ability to self-monitor blood sugar or self-administer insulin. Requests for exceptions will be considered on a case-by-case basis.

2. Documentation that indicates the member's HbA1C level(s) (at least 2 readings representing at least 6 months).

3. Documentation demonstrating that criteria for Initial or Continued Coverage are met as appropriate to the clinical situation as outlined above.

Approved by: _____, MD

Date: 6 November, 2023

Reviewed: _____

Revised: _____