**Medical Necessity Guideline**

| Medical Necessity Guideline (MNG) Title: Therapeutic Continuous Glucose Monitors - CGMs |
|---------------------------------|---------------------------------|------------------|
| MNG #: 023                      | ☒ SCO                           | ☒ Yes ☐ No       |
| Clinical: ☐                      | Operational: ☐                  | Informational: ☐ |
| Medicare Benefit: ☒ Yes ☐ No    | Approval Date: 9/12/2019;       | Effective Date: 04/25/2020 |
| Last Revised Date: 9/12/2020;   | Next Annual Review Date: 9/12/2020; | Retire Date: |

**OVERVIEW:**

“Therapeutic” Continuous Glucose Monitors (CGMs) are approved by the U.S. Food and Drug Administration (FDA) and can be used to replace other blood glucose monitoring testing mechanism to assist with diabetes treatment decisions. Continuous glucose monitoring measures glucose in interstitial fluid, rather than capillary blood. Because CGM devices do not measure blood glucose, different HCPCS and CPT coding are used for these devices and supplies. To meet coverage eligibility requirements, devices must be deemed a “therapeutic” CGM.

CGM devices consist of three components: a glucose sensor; a transmitter; and a receiver (any type of monitor or compatible mobile device). The glucose sensor is inserted beneath an individual’s skin to measure glucose levels in interstitial fluid. The device is connected to the transmitter, which sends the information to the receiver (monitor), where it is displayed for the user; thereby, providing interstitial glucose readings every few minutes, which allows users to visualize glucose measurement trends.

According to CMS, therapeutic CGM may be covered by Medicare if **all the following criteria is met:**

- The beneficiary has diabetes mellitus; and,
- The beneficiary has been using a home blood glucose monitor (BGM) and performing frequent (four or more times a day) BGM testing; and,
- The beneficiary is insulin-treated with three (3) or more daily injections (MDI) of insulin or a continuous subcutaneous insulin infusion (CSII) pump; and,
- The beneficiary’s insulin treatment regimen requires frequent adjustments by the beneficiary based on therapeutic CGM testing results.
- Within six (6) months prior to ordering the CGM, the beneficiary had an in-person visit with the treating practitioner to evaluate his/her diabetes control and determine that the above criteria has been met; and,
- Every six (6) months following the initial prescription of the CGM, the beneficiary has an in-person visit with the treating practitioner to assess adherence to his/her CGM regimen and diabetes treatment plan.

To be included in this category, the device must be **defined as therapeutic CGM,** meaning an individual can make treatment decisions using the device.

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Required Documentation:

- Prescription (orders): Detailed written order from the treating practitioner or practitioner’s office.
- Documentation (notes): Notes of an in person visit with the treating practitioner to evaluate the member’s diabetes control and to determine that medical necessity is met. Visit notes must be within six (6) months prior to ordering the therapeutic CGM.

DECISION GUIDELINES:

Clinical Coverage Criteria:

Members are eligible for this product if they experience:

- Frequent hyperglycemia and hypoglycemia unawareness (blood glucose <70 or lack of an ability to sense the symptoms due to autonomic neuropathy).
- Wide swings in blood glucose levels while on MDI (multiple daily injections) or insulin pump therapy.
- Gastroparesis – partial paralysis of the stomach characterized by nausea, vomiting, and abdominal distension after eating; causing erratic blood glucose levels.
- An inability to check glucose levels as frequently as recommended by their providers due to cognitive impairment, dexterity, or vision issues.

Determination of Medical Necessity:

Additional factors that also impact the medical necessity include:

- Emotional stability, considering an individual's willingness to wear the device for ten (10) to fourteen (14) days without removal
- Ability to problem solve to identify and prevent acute complications

LIMITATIONS/EXCLUSIONS:

The following are exclusions for this product:

- Ability to maintain blood glucose levels using MDI or Insulin Pump Therapy
- Ability to maintain blood glucose levels using oral anti-hyperglycemic agents (OHA)
- Ability to maintain A1C at goal
- Pregnant women and those on dialysis should not use therapeutic CGM, as it has not been evaluated in these populations.
- Those who are critically ill should not use the device; it is not known how different conditions or medications common to the critically ill may affect the performance of the device.

The following requirements for this product may include:

- Existing eating disorder
- History of insulin omission
- History of skipping oral medications
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- Ability to wear sensor for up to fourteen (14) days
- Ability to continue home monitoring via glucometer

KEY CARE PLANNING CONSIDERATIONS:
- Member is willing to adhere to frequent blood glucose monitoring schedule
- Member can demonstrate good record keeping

AUTHORIZATION REQUIREMENTS:
The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not signify whether the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply. This Medical Necessity Guideline is subject to all applicable laws and regulations, Plan Policies and Guidelines, including requirements for prior authorization and other requirements in Provider’s agreement with the Plan (including complying with Plan’s Provider Manual specifications).

Prior Authorization Requirements and Process:
Continuous glucose monitoring (CGM) requires review of documentation, including a review of documentation relating to evaluations by an MD/NP/PA demonstrating the medical necessity of the device. Once deemed medically necessary for this product based on this DST, clinical administration will be notified for record-keeping purposes. Clinical administration will dispense the sensor and record the member’s name, date applied, clinician’s name and lot number.

Procedure Codes:

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<th>Code</th>
<th>Description</th>
<th>Unit of Measurement</th>
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<tr>
<td>K0554</td>
<td>RECEIVER (MONITOR), DEDICATED, FOR USE WITH THERAPEUTIC GLUCOSE CONTINUOUS</td>
<td>1 Unit</td>
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<tr>
<td></td>
<td>MONITOR SYSTEM</td>
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<tr>
<td>K0553</td>
<td>SUPPLY ALLOWANCE FOR THERAPEUTIC CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES</td>
<td>12 Months</td>
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<td>ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE</td>
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REGULATORY NOTES:
1. Medicare Local Coverage Guidelines and Mass Health Coverage Guidelines: Medicare coverage guidelines define medical necessity as “reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”
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2. There is no other medical device comparable, available or suitable for the member requesting the services that is less costly to the Mass Health agency.

Medically necessary devices must be of a quality that meets professionally recognized standards of health and must be substantiated by records including evidence of such medical necessity and quality.

RELATED REFERENCES:
1. Medicare Local Coverage Determination (LCD); Glucose Monitors (L33822)
2. CMS Ruling 1682R
3. Medical Necessity; 130 CMR 428:402
4. FDA 510(k) K183206 Substantial Equivalence Determination Decision Summary Dexcom G6 CGM
5. FDA Premarket Approval Application (PMA) Number: P160030/s017 FreeStyle Libre 14 Day Flash CGM

ATTACHMENTS:

| EXHIBIT A: | EXHIBIT B |

REVISION LOG:

<table>
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<th>REVISION DATE</th>
<th>DESCRIPTION</th>
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<td>9/12/2019</td>
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APPROVALS:

Roberta Capelson, NP  Diabetes Nurse Manager
CCA Senior Clinical Lead [Print] Title [Print]

Signature

8/8/2019

Date

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CCA Senior Operational Lead [Print] Title [Print]
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<tbody>
<tr>
<td>Lori Tishler, MD, MPH</td>
<td>Senior Vice President, Medical Services</td>
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<tr>
<td>CCA CMO or Designee [Print]</td>
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