Dear Physician,

Glucose monitor supplies have consistently been one of the highest sources of errors in medical reviews performed by the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and the Comprehensive Error Rate Testing (CERT) contractor. We know that ordering physicians do work to document the medical necessity for durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The following information is intended to provide you with guidance on Medicare’s coverage and documentation requirements for glucose monitors and testing supplies.

**Coverage**

Glucose monitors and related supplies are covered for patients with diabetes if they or their caregiver can be trained to use the prescribed device appropriately.

The Glucose Monitors Local Coverage Determinations (LCDs) of the DME MACs define the quantity of test strips and lancets that are covered, if the basic criterion above is met.

<table>
<thead>
<tr>
<th>TREATMENT REGIMEN</th>
<th>BASIC COVERAGE TEST STRIPS AND LANCETS</th>
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</thead>
<tbody>
<tr>
<td>INSULIN TREATED</td>
<td>300 PER 3 MONTHS</td>
</tr>
<tr>
<td>NON-INSULIN TREATED</td>
<td>100 PER 3 MONTHS</td>
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Additional quantities of test strips can be considered for coverage if they are documented to be medically necessary – see following section. Coverage is also provided for a lancing device, calibration solution, and replacement batteries.

**Medical Necessity Documentation**

CMS expects that physician records will reflect the care provided to the patient including evidence of the medical necessity for the prescribed frequency of testing. Physicians are not required to fill out additional forms from suppliers or to provide additional information to suppliers unless specifically requested of the supplier by the DME MAC.

As noted below in the Orders section, standard glucose monitors (HCPCS code E0607) require a written order prior to delivery and a face-to-face examination. The face-to-face examination must document that the patient was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. Both the written order and the face-to-face examination must be provided to the supplier before they can dispense the glucose monitor to the patient.
There are several critical issues to address in the patient’s medical record related to medical necessity for glucose testing supplies:

- Basic coverage criteria for the glucose monitor and any related supplies; and,
- If ordering quantities of test strips and lancets that exceed the quantities specified in the LCD:
  - Justification for testing frequency; and
  - Evidence of the patient’s use at this frequency

To satisfy the requirements for the basic coverage criteria, the patient’s medical record should provide information about the following:

- Diagnosis
- Treatment regimen (insulin treated versus non-insulin treated)

To support coverage for quantities of supplies that exceed the limits specified in the LCD, there must be:

- Documentation by the physician in the patient’s medical record of the necessity for the higher frequency of testing. This may include some of the following elements:
  - Names, dosages, and timing of administration of medications used to treat the diabetes;
  - Frequency and severity of symptoms related to hyperglycemia and/or hypoglycemia;
  - Review of patient-maintained log of glucose testing values;
  - Changes in the patient’s treatment regimen as a result of glucose testing results review;
  - Dosage adjustments that the patient should make on their own based on self-testing results;
  - Laboratory tests indicating level of glycemic control (e.g., hemoglobin A1C);
  - Other therapeutic interventions and results.

Not every patient’s medical record will contain all of these elements; however, there must be enough information in the patient’s medical record to support the medical necessity for the quantity of item(s) ordered and dispensed.

- Documentation by the patient of the actual frequency of testing.
  - Logs of self-testing values including the date, time, and results
  - Information about medication dosage adjustments related to the results is also helpful

Orders

For initial dispensing of a standard glucose monitors (code E0607), the supplier must receive a written order prior to delivery of the item to the patient. In addition, you must conduct a face-to-face examination within six (6) months prior to the date of the written order. Both of these documents must be received by the supplier prior to dispensing the item to your patient. This detailed written order must contain, at a minimum, the following elements:

1. Patient’s name
2. Physician’s name
3. Date of the order and the start date, if start date is different from the date of the order
4. Detailed description of the item
5. The prescribing practitioner's National Provider Identifier (NPI)
6. The signature of the ordering practitioner
7. Signature date

Note that testing supplies (e.g., lancets, test strips, control solutions, batteries) are not subject to the written order prior to delivery and face-to-face requirements. For testing supplies, the written order must contain the following elements:

1. Patient’s name
2. Prescribing physician's name
3. Item(s) to be dispensed
4. Frequency of testing (“as needed” is not acceptable)
5. Quantity to be dispensed
6. Number of refills
7. The signature of the ordering practitioner
8. Signature date
9. Date of the order and the start date, if start date is different from the date of the order

A new order for diabetic testing supplies is required only if there is a change in the frequency of testing, a change in supplier, or a new, treating physician.

If the supplier provides you with a prepared “written order” for your signature and date, you should inspect this document carefully. Suppliers must not add unrelated items to the detailed written order, whether requested by the patient or not, in the absence of your explicit approval.

This article is only intended to be a general summary. It is not intended to take the place of the written law, regulations, national or local coverage determinations. The LCD for Glucose Monitors can be found in the Medicare Coverage Database on the CMS website at https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11520&ContrID=140.

Sincerely,

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