



Medicare Coverage of Blood Glucose Monitors and Testing Supplies – JA1008

Note: JA1008 was re-issued to include additional information, regarding special blood glucose monitors for patients with manual dexterity issues. It also clarifies certain information, regarding the content of orders and when new orders are needed.

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Key Words	SE1008, Blood, Glucose, Monitors, Testing, DME, DMEPOS
Contractors Affected	<ul style="list-style-type: none"> • Part A/B Medicare Administrative Contractors (A/B MACs) • Medicare Carriers • Fiscal Intermediaries (FIs), • Durable Medical Equipment MACs (DME MACs), • Regional Home Health Intermediaries (RHHIs)
Provider Types Affected	Physicians, providers, and suppliers submitting claims to Medicare Carriers, DME MACs, FIs, A/B MACs, and/or RHHIs for Medicare covered diabetes benefits provided to Medicare beneficiaries



- SE1008 reminds providers what blood glucose self-testing equipment and supplies are covered for Medicare beneficiaries.
- In addition, SE1008 provides information on prescription/order requirements, quantities, and frequency limits of supplies, and documentation requirements for the beneficiary's medical record. **This is informational only and represents no Medicare policy changes.**

Provider Needs to Know...	<p>Provider Requirements for Prescribing/Ordering a Blood Glucose Monitor and Associated Accessories</p> <ul style="list-style-type: none"> • For Medicare coverage of a blood glucose monitor and associated accessories, the provider must provide a valid prescription (order) which must state to the supplier: <ol style="list-style-type: none"> 1. The item(s) to be dispensed; 2. The frequency of testing ("as needed" is not acceptable);
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3. The physician's signature;
4. The signature date; and,
5. The start date of the order – only required if the start date is different than the signature date.

Coverage of Blood Glucose Monitors and Testing Supplies

- For beneficiaries who are insulin-dependent, Medicare provides coverage for up to 100 test strips and lancets every month and one lancet device every 6 months.
- For beneficiaries who are non-insulin dependent, Medicare provides coverage for up to 100 test strips and lancets every 3 months and one lancet device every 6 months.

Note: Medicare allows additional test strips and lancets **if deemed medically necessary**. See the section titled "Providing Evidence of Medical Necessity." Medicare will not pay for any supplies that are not requested or were sent automatically from suppliers, even if the beneficiary has "authorized" this in advance. This includes lancets, test strips, and blood glucose monitors. Contact with the beneficiary or designee regarding refills should take place no sooner than approximately seven (7) days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the item(s) no sooner than approximately five (5) days prior to the end of usage for the current product(s). This includes lancets, test strips, and blood glucose monitors.

- CR2363 (Transmittal B-03-004) states that glucose test strips and supplies can be billed for up to 3 months of supplies at a time.
- Beginning April 1, 2002, claims for test strips and supplies must be submitted with the appropriate "start" and "end" dates.
- The "start" and "end" dates for each claim can span across 3 months.
- CR2363 is available at <http://www.cms.gov/Transmittals/Downloads/B03004.pdf> on the CMS website.

Orders for Dispensing Items of DME Prosthetics, Orthotics, and Supplies (DMEPOS)

- Suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician.
- This dispensing order must include a description of the item, the beneficiary's name, the physician's name, and the start date of the order.
- Suppliers must maintain the preliminary written order or written documentation of the verbal order.
- This documentation must be available to Medicare contractors upon request.
- If the supplier does not have an order from the treating physician before dispensing an item, the item is non-covered.
- For details, see the *Medicare Program Integrity Manual*, Chapter 5, at <http://www.cms.gov/manuals/downloads/pim83c05.pdf> on the CMS website.

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- For verbal orders, the physician must sign and return to the supplier a written, faxed, or electronic confirmation of the verbal order.
 - On this confirmation the item(s) to be dispensed, frequency of testing, and start date (if applicable) may be written by the supplier, but the confirmation must be reviewed, signed, and dated by the physician.
 - Physicians should inspect these written confirmations carefully.
 - Suppliers must not add unrelated items to the detailed written order, whether requested by the beneficiary or not, in the absence of a dispensing order from the physician for that item.
 - A new order for diabetic testing supplies is required only if there is a change in the frequency of testing or a change in supplier.
 - Renewal orders must contain the same information as initial orders and be submitted to the supplier using one of the methods acceptable for initial orders.

Evidence of Medical Necessity

- CMS expects that physician records will reflect the care provided to the patient. This includes, but is not limited to 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.
- For more information regarding evidence of medical necessity, see the section below titled "Providing Evidence of Medical Necessity."

Note: CR5971 (Transmittal 248) was issued to prohibit the use of stamped signatures. In addition, Medicare requires a legible identifier for services provided/ordered as outlined in CR6698 (Transmittal R327PI). The method used should be hand written or an electronic signature (stamp signatures are not acceptable) to sign an order or other medical record documentation for medical review purposes.

Types of Home Blood Glucose Monitors

- There are several different types of blood glucose monitors that use reflectance meters to determine blood glucose levels.
 - Medicare coverage of these devices varies with respect to both the type of device and the medical condition of the patient for whom the device is prescribed.
 - Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as DME for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use.
 - However, some types of blood glucose monitors which use a reflectance meter specifically designed for home use by diabetic patients may be covered as DME, subject to the conditions and limitations described below.
 - Blood glucose monitors are meter devices that read color changes produced on
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specially treated reagent strips by glucose concentrations in the patient's blood.

- The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and (following instructions which may vary with the device used), inserts it into the device to obtain a reading.
- Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients for whom the device is indicated.
- Home blood glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment.

Coverage of Home Blood Glucose Monitors

- Coverage of home blood glucose monitors is limited to patients meeting the following conditions:
 1. The patient has been diagnosed as having diabetes;
 2. The patient's physician states that the patient is capable of being trained to use the particular device prescribed in an appropriate manner. In some cases, the patient may not be able to perform this function, but a responsible individual can be trained to use the equipment and monitor the patient to assure that the intended effect is achieved. This is permissible if the record is properly documented by the patient's physician; and
 3. The device is designed for home use rather than clinical use.

Blood Glucose Monitoring System for Beneficiaries with the Visual or Manual Impairments

- There are also blood glucose monitoring systems designed especially for use by those with visual or manual dexterity impairments.
- The monitors used in such systems are identical in terms of reliability and sensitivity to the standard blood glucose monitors described above.
- They differ by having such features as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable patients with visual or manual dexterity impairment to use the equipment without assistance.
- These special blood glucose monitoring systems are covered under Medicare if the following conditions are met:
 - The patient and device meet the three conditions listed above for coverage of standard home blood glucose monitors; and
 - The patient's physician certifies that the beneficiary has a visual or manual dexterity impairment severe enough to require use of this special monitoring system.

Note: Section 1833(e) of the Social Security Act precludes payment to any provider of services "unless there has been furnished such information as may be necessary in order to determine the amounts due such provider..." This section maybe reviewed at http://www.socialsecurity.gov/OP_Home/ssact/title18/1833.htm on the Internet.

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- More information on home blood glucose monitors, including additional requirements for monitors with special features, may be reviewed in the following:
 - The *Medicare National Coverage Determinations Manual*, Chapter 1, Part 1 (Coverage Determinations), Section 40.2 (Home Blood Glucose Monitors) at http://www.cms.gov/manuals/downloads/ncd103c1_Part1.pdf, and
 - The Medicare Coverage Database for the local coverage determination (LCD) applicable to the provider area at <http://www.cms.gov/mcd/search.asp?from2=search.asp> (search "Glucose Monitors") on the CMS website.

Reporting Blood Glucose Self-testing Equipment and Supplies

- The Health Care Common Procedure Coding System codes used to report blood glucose self-testing equipment and supplies are shown in the table on page 6 of SE1008.

Providing Evidence of Medical Necessity

- For any DMEPOS item to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable).
 - 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 of the testing supplies.
 - To satisfy the requirements for the basic coverage criteria, the patient's medical record should provide information about the following elements:
 - Diagnosis,
 - Treatment regimen (insulin treated versus non-insulin treated), and
 - Education of the patient or caregiver on the use of the glucose monitor.
 - 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 that 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
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hypoglycemia;

- Review of beneficiary-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 A_{1c}); and
 - Other therapeutic interventions and results;
 - Documentation by the beneficiary of the actual frequency of testing, which includes:
 - Logs of self-testing values including the date, time, and results; and
 - Information about medication dosage adjustments related to the results is also helpful.
 - Not every patient 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.
 - More information, regarding evidence of medical necessity, may be reviewed in the sources below:
 - *The Medicare Program Integrity Manual, Chapter 5 (Items and Services Having Special DME Review Considerations)* at <http://www.cms.gov/manuals/downloads/pim83c05.pdf> and
 - The Medicare Coverage Database for the LCD applicable to the provider's area at <http://www.cms.gov/mcd/search.asp?from2=search.asp> (search "Glucose Monitors") on the CMS website.
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Background

- Blood glucose self-testing equipment and supplies are covered for all people with Medicare Part B who have diabetes. These supplies include:
 - Blood glucose monitors;
 - Blood glucose test strips;
 - Lancet devices and lancets; and
 - Glucose control solutions for checking the accuracy of testing equipment and test strips.
 - Medicare Part B covers the same type of blood glucose testing supplies for people with diabetes whether or not they use insulin. However, the amount of supplies that are covered varies.
 - Medicare provides coverage of blood glucose monitors and associated accessories and supplies for insulin-dependent and non-insulin dependent diabetics based on medical necessity.
 - For more information regarding medical necessity, see the section above titled
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"Providing Evidence of Medical Necessity."

- Diabetes (diabetes mellitus) is defined as a condition of abnormal glucose metabolism using the following criteria:
 - A fasting blood glucose greater than or equal to 126 mg/dL on two different occasions;
 - A 2 hour post-glucose challenge greater than or equal to 200 mg/dL on two different occasions; or
 - A random glucose test over 200 mg/dL for a person with symptoms of uncontrolled diabetes.
 - For more information, see the *Medicare Benefit Policy Manual*, Chapter 15, at <http://www.cms.gov/manuals/Downloads/bp102c15.pdf> on the CMS website.
 - Coverage for diabetes-related DME is provided as a Medicare Part B benefit, and the Medicare Part B deductible and coinsurance or copayment applies.
 - If the provider or supplier does not accept assignment, the amount the beneficiary pays may be higher. In this case, Medicare will provide payment of the Medicare-approved amount to the beneficiary.
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Operational Impact	N/A
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Reference Materials	<p>The MLN Matters® article can be found at http://www.cms.gov/MLNMArticles/downloads/SE1008.pdf on the CMS website.</p> <p>SE1008 reinforces information in SE0738 (<i>An Overview of Medicare Covered Diabetes Supplies and Services</i>, which is available at http://www.cms.gov/MLNMArticles/downloads/SE0738.pdf on the CMS website.</p> <p>The <i>Guide to Medicare Preventive Services</i> is available at http://www.cms.gov/MLNProducts/downloads/mps_guide_Web-061305.pdf on the CMS website.</p> <p>The MLN Matters® articles related to CR5971 and CR6698 may be reviewed at http://www.cms.gov/MLNMArticles/downloads/MM5971.pdf and http://www.cms.gov/mlnmattersarticles/downloads/mm6698.pdf on the CMS website.</p>
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