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Medicare Coverage of Blood Glucose Monitors and Testing Supplies

Important Note: Medicare will only pay claims for DME if the ordering physician and DME supplier are actively enrolled in Medicare on the date of service. Physicians and suppliers have to meet strict standards to enroll and stay enrolled in Medicare. If you are not enrolled on the date the prescription is filled or re-filled, Medicare will not pay the submitted claims. It is also important to tell the Medicare beneficiary if you are not participating in Medicare before you order DME. If you do not have an active record, please see the following fact sheet containing information on how to **enroll, revalidate your enrollment and/or make a change:** https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedEnroll_PhysOther_FactSheet_ICN903768.pdf on the CMS website.

Note: The article was revised on December 21, 2015, to include the "Important Note" above. All other information remains unchanged.

Provider Types Affected

This article is informational for physicians, providers, and suppliers submitting claims to Medicare contractors (carriers, Durable Medical Equipment Medicare Administrative Contractors (DME MACs), Fiscal Intermediaries (FIs), A/B Medicare Administrative Contractors (A/B MACs), and/or Regional Home Health Intermediaries (RHHIs)) for Medicare covered diabetes benefits provided to Medicare beneficiaries.

What You Need to Know

This special edition article is being provided by the Centers for Medicare & Medicaid Services (CMS) to remind providers what blood glucose self-testing equipment and supplies are covered for Medicare beneficiaries. In addition, prescription/order

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requirements, quantities and frequency limits of supplies, and documentation requirements for the beneficiary's medical record are detailed. This article reinforces information supplied in MLN Matters® article SE0738, which is available at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0738.pdf> on the Centers for Medicare & Medicaid Services (CMS) website. **This article is informational only and represents no Medicare policy changes.**

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 below titled '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.

See the Medicare Benefit Policy Manual, Chapter 15, at

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf> on the CMS website for more information.

Coverage for diabetes-related Durable Medical Equipment (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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Prescribing/Ordering a Blood Glucose Monitor and Associated Accessories

Provider Requirements

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:

1. The item(s) to be dispensed;
2. The frequency of testing (“as needed” is not acceptable);
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.

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 below 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. 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.

CR 2363 (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. You can find CR 2363 at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/B03004.pdf> on the CMS website.

Suppliers may dispense most items of Durable Medical Equipment Prosthetics, Orthotics, and Supplies (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 and 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. See the “Medicare Program Integrity Manual”, Chapter 5, at <http://www.cms.gov/Regulations-and-Guidance/Guidance/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.

CMS expects that physician records will reflect the care provided to the patient including, but 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: CR 5971 (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 CR 6698 (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. You can review MLN Matters® articles related to CR 5971 and CR 6698 at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM5971.pdf> and <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm6698.pdf> on the CMS website.

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.

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Blood glucose monitors are meter devices that read color changes produced on 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. Studies indicate that the patient's ability to carefully follow proper procedures is critical to obtaining satisfactory results with these devices. In addition, the cost of the devices, with their supplies, limits economical use to patients who must make frequent checks of their blood glucose levels.

Accordingly, 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.

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..." See http://www.socialsecurity.gov/OP_Home/ssact/title18/1833.htm on the Internet.

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For more information on home blood glucose monitors, including additional requirements for monitors with special features, see the Medicare National Coverage Determinations Manual, Chapter 1, Part 1 (Coverage Determinations), Section 40.2 (Home Blood Glucose Monitors) at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/ncd103c1_Part1.pdf on the CMS website and the Medicare Coverage Database for the local coverage determination (LCD) applicable to your area at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> (search “Glucose Monitors”).

The Health Care Common Procedure Coding System (HCPCS) codes used to report blood glucose self-testing equipment and supplies are shown in the following table:

HCPCS Codes for Blood Glucose Self-Testing Equipment and Supplies

HCPCS Code	HCPCS Code Descriptor
A4233	Alkaline battery for glucose monitor
A4234	J-cell battery for glucose monitor
A4235	Lithium battery for glucose monitor
A4236	Silver oxide battery glucose monitor
A4253	50 test strips for a blood glucose monitor
A4256	Calibration solutions
A4258	Spring-powered lancing device
A4259	100 lancets for a blood glucose monitor
E0607	Home blood glucose monitor
E2100	Home blood glucose monitor w voice capability (for visual impairment)
E2101	Home blood glucose monitor w integrated lancing/blood collection (for manual dexterity impairment)

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

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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)
- 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. 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 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});
 - Other therapeutic interventions and results;
- Documentation by the beneficiary 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.

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.

For more information regarding evidence of medical necessity, see the Medicare Program Integrity Manual, Chapter 5 (Items and Services Having Special DME Review Considerations) at <http://www.cms.gov/Regulations-and->

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[Guidance/Guidance/Manuals/downloads/pim83c05.pdf](http://www.cms.gov/Guidance/Guidance/Manuals/downloads/pim83c05.pdf) on the CMS website, and the Medicare Coverage Database for the local coverage determination (LCD) applicable to your area at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx> (search “Glucose Monitors”).

Additional Information

You can find SE0738, An Overview of Medicare Covered Diabetes Supplies and Services at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0738.pdf> on the CMS website.

You can also find The Guide to Medicare Preventive Services at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/mps_guide_Web-061305.pdf and the Medicare Preventive Services Brochure at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/DiabetesSvcs.pdf> on the CMS website.

If you have any questions, please contact your carrier, FI, A/B MAC, RHHI, or DME MAC at their toll-free number, which may be found at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/provider-compliance-interactive-map/index.html> on the CMS website.

Important information for physicians and non-physician practitioners who opt out of Medicare and/or elect to order and certify services to Medicare beneficiaries is available in MLN Matters® Article SE1311 at <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE1311.pdf> on the CMS website.

Document History

Date	Description
December 21, 2015	The article was revised on December 21, 2015, to include the "Important Note" near the top of page 1.
January 26, 2015	This article was revised to include a link to article SE1311, which includes important information for physicians and non-physician practitioners who opt out of Medicare and/or elect to order and certify services to Medicare beneficiaries.

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