DMERC
Medicare
News

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Glucose Monitors

Effective for dates of services on or after July 1, 1998, Medicare coverage for glucose monitors and related accessories and supplies is being expanded to include patients who are not being treated with insulin injections. (Prior to this date, Medicare only covered these items for patients who were being treated with insulin injections.)

The patient must meet at least the following basic criteria:

1) The patient has diabetes (ICD-9 codes 250.00-250.93) which is being treated by a physician; and

2) The glucose monitor and related accessories and supplies have been ordered by the physician who is treating the patient's diabetes; and

3) The device is designed for home use.

The physician treating the beneficiary's diabetes must state on an order to the supplier the diagnosis (ICD-9-CM or narrative) of diabetes, whether or not the beneficiary is being treated with insulin injections, the item / supplies / accessories needed, the quantity to be dispensed, and the frequency with which the beneficiary should use them. An order which merely states "as needed" will not be considered valid for Medicare.

This order will be valid for 6 months, at which time the physician will have to renew it in order for the beneficiary to continue to receive covered test strips and lancets. Renewal of the order must be initiated by either the treating physician, the beneficiary or the beneficiary's caregiver. A supplier may not initiate an order for these items. Initiation of the renewal should be dependent upon the beneficiary's use of these supplies, and the renewal order must contain the same information as described above for initial orders.

DMERCs will only pay for glucose monitoring supplies that are medically necessary. Medical necessity requires that the beneficiary be under the care of a physician and the frequency of testing be determined by the physician treating the beneficiary's diabetes.

Quantities of home glucose monitor supplies that are not prescribed according to the above criteria will be denied as not medically necessary.

Documentation Requirements

The supplier must have an original order which is signed and dated by the physician who is treating the beneficiary's diabetes. For supplies, the order must list the items that are to be dispensed and the frequency of testing. A narrative diagnosis and / or ICD-9-CM diagnosis code must be present on each order for a glucose monitor or related accessory or supply. The order must also include a statement indicating whether or not the patient is being treated with insulin injections. The supplier must obtain a new written order from the treating physician every 6 months.

An ICD-9-CM diagnosis code describing the condition which necessitates glucose testing must be included on each claim for the monitor, accessories, and supplies. The supplier should continue to use the ZX modifier for insulin-treated diabetics as described in the current DMERC RMRP for home blood glucose monitors.

Policy Revision

The information above provides a general description of the expanded benefit for non-insulin-treated diabetics which went into effect for dates of service on or after 7 / 1 / 98. In addition, the current DMERC policy on Home Blood Glucose Monitors remains in effect (except for the statements that indicate that coverage is limited to insulin-treated diabetics).

What follows is an Interim Medical Policy on Glucose Monitors. This is a revision of the existing policy and establishes coverage criteria and documentation requirements which implement the expanded benefit. The interim policy is effective for claims with dates of service on or after 10 / 1 / 98.

As with all new or revised policies, this policy has been sent for comment to national organizations representing manufacturers, suppliers, physicians, and other healthcare professionals involved in the ordering, provision, or use of glucose monitors in the home. If, based on comments received from these groups, the DMERCs decide to revise this policy, the revision will be published in a future bulletin.

Home Blood Glucose Monitors

HCPCS Codes:

The appearance of a code in this section does not necessarily indicate coverage.

Equipment:

E0607 Home blood glucose monitor

E0609 Blood glucose monitor with special features (e.g., voice synthesizers, automatic timers, etc.)

Accessories/ Supplies:

A4244 Alcohol or peroxide, per pint

A4245 Alcohol wipes, per box

A4246 Betadine or pHisohex solution, per pint

A4247 Betadine or iodine swabs/wipes, per box

A4250 Urine test or reagent strips or tablets (100 tablets or strips)

A4253 Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips

A4254 Replacement battery, any type, for use with medically necessary home blood glucose monitor owned by patient, each

A4255 Platforms for home blood glucose monitor, 50 per box

A4256 Normal, low and high calibrator solution/chips

A4258 Spring-powered device for lancet, each

A4259 Lancets, per box of 100

HCPCS Modifiers:

KS Glucose monitor supply for diabetic beneficiary not treated by insulin

ZX Specific requirements found in the Documentation section of the medical policy have been met and evidence of this is available in the supplier's records.

Benefit Category:

Durable Medical Equipment

Reference:

Coverage Issues Manual 60-11 (addresses insulin-treated diabetics)

Program Memorandum B98-26 (addresses non-insulin-treated diabetics)

Definitions:

Insulin-treated means that the patient is receiving insulin injections to treat their diabetes. Insulin does not exist in an oral form and therefore patients taking oral medication to treat their diabetes are not insulin-treated.

A severe visual impairment is defined as a best corrected visual acuity of 20/200 or worse.

Coverage and Payment Rules:

Home blood glucose monitors are covered for patients who are diabetics and who can better control their blood glucose levels by checking these levels and appropriately contacting their attending physician for advice and treatment.

To be eligible for coverage, the patient must meet the following basic criteria:

1) The patient has diabetes (ICD-9 codes 250.00-250.93) which is being treated by a physician; and

2) The glucose monitor and related accessories and supplies have been ordered by the physician who is treating the patient's diabetes; and

3) The patient (or the patient's caregiver) has successfully completed training or is scheduled to begin training in the use of the monitor, test strips, and lancets; and

4) The patient (or the patient's caregiver) is capable of using the test results to assure the patient's appropriate glycemic control; and

5) The device is designed for home use.

Blood glucose monitors with such features as voice synthesizers and specially designed arrangements of supplies and materials to enable the visually-impaired to use the equipment without assistance (E0609) are covered when the following conditions are met:

1) The patient and device meet the conditions listed above for coverage of standard home blood glucose monitors; and

2) The patient's physician certifies that he or she has a visual impairment severe enough to require use of this special monitoring system.

Lancets (A4259), blood glucose test reagent strips (A4253), and spring powered devices for lancets (A4258) are covered for patients for whom the glucose monitor is covered. More than one spring powered device (A4258) per 6 months will rarely be medically necessary.

The quantity of test strips (A4253) and lancets (A4259) that are covered depends on the usual medical needs of the diabetic patient according to the following guidelines:

- For a patient who is not currently being treated with insulin injections, up to 50 test strips every 2 months and 100 lancets every 4 months are covered if criteria (a) – (c) are met:

- For a patient who is currently being treated with insulin injections, up to 100 test strips and 100 lancets every month are covered if criteria (a) – (c) are met:

  a) The coverage criteria (1-5) listed above for a glucose monitor are met; and

  b) The supplier of the test strips and lancets maintains in its records the order from the treating physician; and

  c) The beneficiary has nearly exhausted the supply of test strips and lancets that have been previously dispensed.

- For a patient who is not currently being treated with insulin injections, more than 50 test strips every 2 months and 100 lancets every 4 months are covered if, in addition to criteria (a) - (c) listed above, criteria (d) - (f) are met:

- For a patient who is currently being treated with insulin injections, more than 100 test strips and 100 lancets every month are covered if, in addition to criteria (a) - (c) listed above, criteria (d) - (f) are met:

  d) The treating physician justifies (see Documentation section) the need for the additional strips for that particular patient; and

  e) The treating physician has seen the patient and has evaluated their diabetes

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control within 6 months prior to ordering the additional strips and lancets; and

f) The treating physician has maintained documentation in the patient's medical record of blood glucose test results and any change in the beneficiary's diabetes medication over one full month within 6 months prior to dispensing the additional strips and lancets. (The documentation must consist of a copy of a written log recorded by the patient or caregiver or a printout from the monitor's memory, if applicable, which includes the date, approximate time, and result of each test).

For quantities of test strips or lancets that exceed the utilization guidelines, if documentation that criteria (d-f) listed above does not accompany the claim (see Documentation section), payment will be based on 50 test strips every 2 months and 100 lancets every 4 months for a patient who is not insulin-treated or 100 test strip and lancets per month for a patient who is insulin-treated.

A beneficiary or their caregiver must specifically request refills of glucose monitor supplies before they are dispensed. The request must be initiated by the beneficiary or their caregiver. A supplier may not initiate a refill of an order. If the request is in the form of a verbal, fax, mail, or similar request, the supplier must maintain documentation of this in their records. If the request is in the form of a purchase in person at a retail establishment, the supplier does not have to maintain documentation of this. The supplier must not automatically dispense a quantity of supplies on a predetermined regular basis, even if the beneficiary has "authorized" this in advance.

A supplier should not dispense more than a 2-month supply of test strips and / or lancets at a time (except that a 4-month supply of lancets may be dispensed to a non-insulin-treated patient).

Alcohol or peroxide (A4244, A4245), Betadine or pHisohex (A4246, A4247) are noncovered since these items are not required for the proper functioning of the device.

Urine test reagent strips or tablets (A4250) are noncovered since they are not related to this equipment.

Coding Guidelines:

Blood glucose test or reagent strips that use a visual reading and are not used in a glucose monitor should be coded A9270 (noncovered item or service). Do not use code A4253 for these items.

In the following table, a Column II code is included in the allowance for the corresponding Column I code when provided at the same time.

Column I	Column II
E0607	A4254, A4256, A4258
E0609	A4254, A4256, A4258

Documentation:

The supplier must have an original order which is signed and dated by the physician who is treating the patient's diabetes. For supplies, the order must list the items and number that are to be dispensed and the frequency of testing. A narrative diagnosis and / or ICD-9-CM diagnosis code must be present on each order for a glucose monitor or related accessory or supply. The order must also include a statement indicating whether the patient is being treated with insulin injections. The supplier is required to have a new written order containing the same information from the treating physician every 6 months.

The ICD-9-CM diagnosis code describing the condition which necessitates glucose testing must be included on each claim for the monitor, accessories, and supplies.

If the order indicates that the patient is: 1) diabetic and 2) is being treated with insulin injections, the ZX modifier must be added to the code for the monitor and each related supply on every claim submitted. The ZX modifier may only be used when requirements 1 and 2 are met. The ZX modifier must not be used for a patient who is not treated with insulin injections.

For those patients who are not insulin treated, the KS modifier must be added to the code for the monitor and supplies on each claim submitted.

If the claim is for more than 50 test strips every 2 months or 100 lancets every 4 months for a patient who is not insulin-treated (KS modifier present) or more than 100 test strip or lancets per month for a patient who is insulin-treated (ZX modifier present), and if the supplier has a copy of signed and dated documentation from the treating physician which indicates whether criteria (d), (e), and (f) listed above have been met, the claim must be sent hard copy, accompanied by a copy of that documentation. A suggested form for collecting the information in (d) and (e) is attached. Answers on any form used to obtain this information may not be completed by the supplier or anyone in a financial relationship with the supplier. The information on any form must be supported by information in the patient's medical record. A copy of the written log of home blood glucose test results, as described in criterion (f), must be reviewed by the treating physician, forwarded to the supplier, and must also accompany the claim. All of the information described must be submitted with each claim for more than the usual quantity of supplies in order for coverage of the additional supplies to be considered. (Note: the data collection form and extra documentation are only required on claims seeking Medicare coverage for more than the usual quantity of test strips or lancets.)

The medical necessity for E0609 must be documented by a narrative statement from the physician which includes the patient's visual acuity

Refer to the *Supplier Manual* for more information on orders, medical records, and supplier documentation.

Effective Date:

Claims with dates of service on or after October 1, 1998

This is a revision to a previously published policy.

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Statement of Treating Physician
Glucose Monitor Test Strips Exceeding Policy Guidelines

Patient Name: _____ HIC #: _____

This information must be completed by the treating physician only if the patient:

- is being treated with insulin and is expected to use more than 100 test strips per month,
  or
- is not being treated with insulin and is expected to use more than 50 test strips per 2 months.

If these conditions are met, this information must be provided to the patient or to the supplier of the test strips and lancets every 6 months along with a copy of a recent one month's log of the patient's home blood glucose test results.

The information below may not be completed by the supplier or anyone in a financial relationship with the supplier.

Circle Y for Yes, N for No, unless otherwise noted

Y N 1) Do you treat this patient for diabetes?

Y N 2) Is the patient currently using insulin injections to control their diabetes?

_____ 3) What was the date of the last time you saw the patient for their diabetes?

4) Give specific reasons for quantities of test strips which exceed the policy guidelines listed above. (If the reason is related to the initiation or dosage change of a drug, give name and date.)

_____

_____

_____

Physician name (printed or typed): _____

Physician signature: _____

Physician UPIN: _____ Date signed: _____

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