

## Local Medical Review Policies (LMRPs)

### 14.06 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
- E0620 Skin piercing device for collection of capillary blood, laser, each
- E2100 Blood glucose monitor with integrated voice synthesizer
- E2101 Blood glucose monitor with integrated lancing/blood sample collection

#### 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
- A4257 Replacement lens shield cartridge for use with laser skin piercing device, each
- 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
- KX Specific required documentation on file

#### Benefit Category

Durable Medical Equipment

#### References

Coverage Issues Manual 60-11

#### 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 best corrected visual acuity of 20/200 or worse.

A renewal of an order is the writing of a new order by the treating physician. A refill of an order is the actual dispensing of the item to the beneficiary based on an existing valid order.

Code A4256 describes control solutions containing high, normal, and low concentrations of glucose that can be applied to test strips to check the integrity of the test strips. This code does not describe the strip or chip which is included in a vial of test strips and which calibrates the glucose monitor to that particular vial of test strips.

Laser skin lancing devices use laser technology to pierce the skin in order to obtain capillary blood for use in home blood glucose monitors.

### **Coverage And Payment Rules**

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this medical policy, "reasonable and necessary" are defined by the following 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 all of 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 lancing devices; 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.

For all glucose monitors and related accessories and supplies, if the basic coverage criteria (1)-(5) are not met, the items will be denied as not medically necessary.

Home blood glucose monitors with special features (E2100, E2101) are covered to enable the visually-impaired to use the equipment without assistance. Codes E2100 or E2101 are covered when the basic coverage criteria (1)-(5) are met and the treating physician certifies that the patient has a severe visual impairment (i.e. best corrected visual acuity of 20/200 or worse) requiring use of this special monitoring system.

In addition, E2101 is covered when the basic coverage criteria (1)-(5) are met and the treating physician certifies that the patient has an impairment of manual dexterity severe enough to require the use of this special monitoring system.

If an E2100 or E2101 glucose monitor is provided and basic coverage criteria (1)-(5) are met but the additional criterion is not met, payment will be based on the allowance for the least costly medically appropriate alternative, E0607.

Lancets (A4259), blood glucose test reagent strips (A4253), glucose control solutions

(A4256), spring powered devices for lancets (A4258), and replacement lens shield cartridge (A4257) for use with laser skin piercing device 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 medical necessity for a laser skin piercing device (E0620) has not been established. If an E0620 is ordered for use with a covered home blood glucose monitor, payment will be based on the allowance for the least costly medically appropriate alternative (A4258). In addition, since E0620 is not medically necessary, replacement lens shield cartridges (A4257) are also considered not medically necessary. If A4257 is ordered for use with an E0620, payment will be based on the allowance for the least costly medically appropriate alternative (A4259).

The quantity of test strips (A4253), lancets (A4259), and replacement lens shield cartridges (A4257) 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 100 test strips and up to 100 lancets or one lens shield cartridge every 3 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 up to 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(c) are met:

For a patient who is not currently being treated with insulin injections, more than 100 test strips and up to 100 lancets or one lens shield cartridge every 3 months are covered if criteria (a)-(f) are met:

For a patient who is currently being treated with insulin injections, more than 100 test strips and up to 100 lancets or one lens shield cartridge every month are covered if criteria (a)-(f) are met:

- a. Coverage criteria (1)-(5) listed above for a glucose monitor are met.
- b. The supplier of the test strips and lancets, or lens shield cartridge maintains in its records the order from the treating physician.
- c. The beneficiary has nearly exhausted the supply of test strips and lancets, or useful life of one lens shield cartridge previously dispensed.
- d. The treating physician has ordered a frequency of testing that exceeds the utilization guidelines and has documented in the patient's medical record the specific reason for the additional materials for that particular patient.
- e. The treating physician has seen the patient and has evaluated their diabetes control within 6 months prior to ordering quantities of strips and lancets, or lens shield cartridges that exceed the utilization guidelines.
- f. If refills of quantities of supplies that exceed the utilization guidelines are dispensed, there must be documentation in the physician's records (e.g. a specific narrative statement that adequately documents the frequency at which the patient is actually testing or a copy of the beneficiary's log) or in the supplier's records (e.g. a copy of the beneficiary's log) that the patient is actually testing at a frequency that corroborates the quantity of supplies that have been dispensed. If the patient is regularly using quantities of supplies that exceed the utilization guidelines, new documentation must be present at least every six months.

If criteria (a)-(c) are not met, all testing supplies will be denied as not medically necessary. If quantities of test strips, lancets or lens shield cartridges that exceed the utilization guidelines are

provided and criteria (d)-(f) are not met, the amount in excess will be denied as not medically necessary.

**A beneficiary or their caregiver must specifically request refills of glucose monitor supplies before they are dispensed.** 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 3-month supply of test strips, lancets or lens shield cartridges at a time.

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 used with a glucose monitor.

### **Coding Guidelines**

For glucose test strips (A4253), 1 unit of service = 50 strips. For lancets (A4259), 1 unit of service = 100 lancets.

Blood glucose test or reagent strips that use a visual reading and are not used in a glucose monitor must 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
E2100	A4254, A4256, A4258
E2101	A4254, A4256, A4258

Suppliers should contact the Statistical Analysis Durable Medical Equipment Regional Carrier (SADMERC) for guidance on the correct coding of these devices.

### **Documentation**

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" (42 U.S.C. §1395l(e)). It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available to the DMERC upon request.

The supplier must have an order that is signed and dated by the physician who is treating the patient's diabetes. For supplies, the order must list the items that are to be dispensed and the specific frequency of testing. An order that only states "as needed" will result in those items being denied as not medically necessary. A narrative diagnosis and/or ICD-9 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 from the treating physician every 12 months. This renewal of the order must also contain the information specified above.

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

If the order indicates that the patient is being treated with insulin injections, the KX modifier must be added to the code for the monitor and each related supply on every claim submitted. The KX modifier must not be used for a patient who is not treated with insulin injections.

If the order indicates that the patient is not being treated with insulin injections, the KS modifier must be added to the code for the monitor and each related supply on every claim submitted.

Additional documentation requirements apply to: (1) a diabetic patient who is not insulin-treated (KS modifier present) and whose prescribed frequency of testing is more often than once per day, or (2) a diabetic patient who is insulin-treated (KX modifier present) and whose prescribed frequency of testing is more often than three times per day. When refills for quantities of supplies that exceed the utilization guidelines are dispensed, the documentation as described in criteria (d)-(f) in the Coverage and Payment Rules section must be available to the DMERC on request.

The medical necessity for E2100 or E2101 in a patient with impaired visual acuity must be documented by a narrative statement from the physician that must include the patient's specific numerical visual acuity (e.g. 20/400) and that this result represents "best corrected" vision. This documentation should be attached to a hard copy claim or entered into the HAO record of an electronic claim.

Similarly, claims for E2101 for patients with impaired manual dexterity must be documented by a narrative statement from the physician that includes an explanation of the patient's medical condition necessitating the monitor with special features. This information does not have to be routinely sent in with the claim, but must be available to the DMERC on request.

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 July 1, 2002.

This is a revision to a previously published policy.