

LCD for Glucose Monitors (L11510)

Contractor Information

Contractor Number

00635

Contractor Type

DMERC

LCD Information

LCD ID Number

L11510

LCD Title

Glucose Monitors

Contractor's Determination Number

GLUC

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CMS National Coverage Policy

CMS Pub. 100-3, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2

Original Determination Effective Date

For services performed on or after 10/01/1993

Original Determination Ending Date**Revision Effective Date**

For services performed on or after 01/01/2006

Revision Ending Date**Indications and Limitations of Coverage and/or Medical Necessity**

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, the criteria for "reasonable and necessary" are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted to the DMERC. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not medically necessary.

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 the treating physician maintains records reflecting the care provided including, but not limited to, evidence of medical necessity for the prescribed frequency of testing; 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 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.

Code E2101 is also covered for those with impairment of manual dexterity 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. Coverage of E2101 for patients with manual dexterity impairments is not dependent upon a visual impairment.

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 and purchased for use with a covered home blood glucose monitor, payment will be based on the allowance for the least costly medically appropriate alternative (A4258). If an E0620 is ordered and rented for use with a covered home blood glucose monitor, since the E0620 is in a different payment category than A4258 and a least costly medically appropriate alternative payment cannot be made, it will be denied as not medically necessary. 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). Similarly, if the E0620 is rented, the replacement lens shield cartridges (A4257) cannot be paid based on a least costly medically appropriate payment methodology and will be denied as not medically necessary.

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 more than 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 more than 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.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers should stay attuned to atypical utilization patterns on behalf of their clients and verify with the ordering physicians that the atypical utilization is, in fact, warranted. Regardless of utilization, a supplier must not dispense more than a 3-month quantity of glucose testing supplies at a time.

Suppliers may contact the treating physician to renew an order; however, the request for renewal may only be made with the beneficiary's continued monthly use of testing supplies and only with the beneficiary's request to the supplier for order renewal.

An order refill does not have to be approved by the ordering physician; however, 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.

Coverage Topic

Diabetic Supplies
Durable Medical Equipment

Coding Information**Bill Type Codes:**

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes

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

HCPCS MODIFIERS:

EY No physician or other licensed health care provider order for this item or service.
KS Glucose monitor supply for diabetic beneficiary not treated by insulin.
KX Specific required documentation on file.

HCPCS CODES:**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

ACCESSORIES/SUPPLIES:

A4233	REPLACEMENT BATTERY, ALKALINE (OTHER THAN J CELL), FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH
A4234	REPLACEMENT BATTERY, ALKALINE, J CELL, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH
A4235	REPLACEMENT BATTERY, LITHIUM, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH

A4236	REPLACEMENT BATTERY, SILVER OXIDE, FOR USE WITH MEDICALLY NECESSARY HOME BLOOD GLUCOSE MONITOR OWNED BY PATIENT, EACH
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
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
A9275	HOME GLUCOSE DISPOSABLE MONITOR, INCLUDES TEST STRIPS
ICD-9 Codes that Support Medical Necessity	
Not specified	
Diagnoses that Support Medical Necessity	
Not specified	
ICD-9 Codes that DO NOT Support Medical Necessity	
Not specified	
ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation	
Diagnoses that DO NOT Support Medical Necessity	
Not specified	

General Information

Documentation Requirements

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. §13951 (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.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available to the DMERC upon request. Items billed to the DMERC before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

The order for home blood glucose monitors and/or diabetic testing supplies must include all of the following elements:

1. All item(s) to be dispensed;
2. The specific frequency of testing;
3. The treating physician's signature;
4. The date of the treating physician's signature;
5. A start date of the order - only required if the start date is different than the signature date.

An order that only states "as needed" will result in those items being denied as not medically necessary. A new order must be obtained when there is a change in the testing frequency.

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

If 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 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 Indications and Limitations of Coverage and/or Medical Necessity 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 information does not have to be sent in with the claim but must be substantiated in the patient's medical record and available to the DMERC upon request.

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 sent in with the claim, but must be available to the DMERC on request.

Suppliers are not prohibited from creating data collection forms in order to gather medical necessity information; however, the DMERC will not rely solely on those forms to prove the medical necessity of services provided. Suppliers must not attribute any self-generated forms or data collection requests to the Medicare Program, CMS, or the DMERCs. Physicians are not required to fill out additional forms from suppliers or to provide additional forms to suppliers or to provide additional information to suppliers unless specifically requested by the supplier per the DMERC.

Refer to the Supplier Manual for more information on documentation requirements.

Appendices

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.

An order renewal is the act of obtaining an order for an additional period of time beyond that previously ordered by the treating physician.

An order refill is the act of replenishing quantities of previously ordered items during the time period in which the current order is valid.

Utilization Guidelines

Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision

Reserved for future use.

Advisory Committee Meeting Notes**Start Date of Comment Period****End Date of Comment Period****Start Date of Notice Period****Revision History Number**

003

Revision History Explanation

Revision Effective Date: 01/01/2006

HCPCS CODES AND MODIFIERS:

Added: A4233, A4234, A4235, A4236, A9275

Deleted: A4254

Revision Effective Date: 07/01/2005

LMRP converted to LCD and Policy Article

DOCUMENTATION REQUIREMENTS:

Eliminated certain required elements from order

Revision Effective Date: 04/01/2003

LMRP name changed to Glucose Monitors.

HCPCS CODES AND MODIFIERS:

Added: EY

INDICATIONS AND LIMITATIONS OF COVERAGE:

Adds standard language concerning coverage of items without an order.

DOCUMENTATION REQUIREMENTS:

Adds standard language concerning use of EY modifier for items without an order.

The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

9/01/2002 - Revised definitions of order renewal and order refill. Clarified that coverage of E2101 for beneficiaries with manual dexterity impairments is not dependent on visual impairment. Emphasized that suppliers have an obligation to monitor a beneficiary's utilization of supplies and dispense supplies accordingly. Stated specific elements required for orders. Clarified the DMERC position on the use of data collection forms. Removed bundling table.

03/01/2002 - Added new HCPCS codes E0620, E2100, E2101 and A4257. Added definition of E0620 (skin piercing device for collection of capillary blood, laser, each). Deleted E0609 and crosswalk to E2100 and E2101. Added coverage and payment rules for E2101. Updated ICD-9 code range for diabetes mellitus. Replaced ZX with KX modifier. Changed timeframe for new prescription from every 6 months to every 12 months. Applied least costly alternative authority to E0620 and A4257.

03/01/1999 - Updated Coverage and Payment Rules section adding reasonable and necessary language and criteria (f) regarding utilization.

12/01/1998 - Added definitions for renewal order and A4256. Updated coverage and payment rules allowing coverage for non-insulin treated diabetics. Added KS modifier for non-insulin treated diabetics. Updated utilization guidelines for test strips/lancets for insulin and non-insulin treated diabetics.

12/01/1997 - Code XX003 (platforms) changed to A4255. Updated coding guidelines removing effective date for A4254 & A4258 and added bundling table.

09/01/1996 - Changed codes: K0267 to A4254 and K0131 to A4258. Deleted code XX002 (test strips, per 25). Added effective dates for A4254 & A4258.

09/01/1995 - Added code K0267 (replacement battery for monitor). Added utilization guidelines for test strips/lancets to the Coverage and Payment Rules section.

06/01/1995 - Added ZX modifier. Added definition for insulin-treated diabetic. Moved Indications information to Coverage and Payment Rules section. Removed criteria 2) concerning documentation in the Coverage and Payment Rules section. Updated coding guidelines for number of services for A4259 from "per 50" to "per 100." Updated coding guidelines for XX002 to exclude claim submission to DMERC; instructed suppliers to use A4253 instead. Updated Documentation section adding information regarding use of ZX modifier and utilization guidelines for test strips/lancets.

12/01/1993 - Added code XX002 (test strips, per 25). Included utilization guidelines in the Coverage and Payment Rules section for XX002. HAO corrected to HAO in Documentation section.

Last Reviewed On Date

Related Documents

Article(s)

A33753 - Glucose Monitors – Policy Article – Effective January 2006

LCD Attachments

There are no attachments for this LCD

Other Versions

Updated on 05/27/2005 with effective dates 07/01/2005 - N/A

Updated on 06/30/2005 with effective dates 04/01/2003 - 06/30/2005

Contractor Information

Contractor Number

00635

Contractor Type

DMERC

Article Information

Article ID Number

A33753

Article Type

Article

Key Article

Yes

Article Title

Glucose Monitors – Policy Article – Effective January 2006

Original Article Effective Date

07/01/2005

Article Revision Effective Date

01/01/2006

Article Text

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES

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.

Reflectance colorimeter devices used for measuring blood glucose levels in clinical settings are not covered as durable medical equipment for use in the home because their need for frequent professional re-calibration makes them unsuitable for home use.

Home blood glucose disposable monitor, including test strips (A9275) is noncovered because these monitors do not meet the definition of DME.

CODING GUIDELINES

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.

A laser skin lancing device (E0620) uses laser technology to pierce the skin in order to obtain capillary blood for use in home blood glucose monitors.

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.

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

Coverage Topic

Diabetic Supplies
Durable Medical Equipment

Coding Information

ICD-9 Codes that are Covered

The presence of an ICD-9 code listed in this section is not sufficient by itself to assure coverage. Refer to the Article Text field, Non-Medical Necessity Coverage and Payment Rules section for other coverage criteria and payment information.

250.00 - DIABETES MELLITUS WITHOUT MENTION OF COMPLICATION, TYPE II OR UNSPECIFIED
250.93 TYPE, NOT STATED AS UNCONTROLLED - DIABETES WITH UNSPECIFIED COMPLICATION, TYPE I [JUVENILE TYPE], UNCONTROLLED

ICD-9 Codes that are Not Covered

All codes not specified in the previous section.

Other Information

Revision History Explanation

Revision Effective Date: 01/01/2006

MON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added non-coverage statement for disposable blood glucose monitor.

Effective Date: 07/01/2005

LMRP converted to LCD and Policy Article

NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:

Added noncoverage statement for reflectance colorimeter devices used in clinical settings.

Related Documents

LCD(s)

L11510 - Glucose Monitors