Local Coverage Determination (LCD)

Glucose Monitors

L33822

Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

LCD Information

Document Information

LCD ID
L33822

LCD Title
Glucose Monitors

Proposed LCD in Comment Period
N/A

Source Proposed LCD
DL33822

Original Effective Date
For services performed on or after 10/01/2015

Revision Effective Date
For services performed on or after 10/01/2024

Revision Ending Date
N/A

Retirement Date
N/A

Notice Period Start Date
03/02/2023

Notice Period End Date
04/15/2023

Issue

Issue Description

The LCD is revised to update the long descriptor for HCPCS code A4271, based on CMS HCPCS coding determinations.

Issue - Explanation of Change Between Proposed LCD and Final LCD

No proposed LCD issued.

CMS National Coverage Policy

CMS Pub. 100-03, (Medicare National Coverage Determinations Manual), Chapter 1, Section 40.2

Coverage Guidance

Coverage Indications, Limitations, 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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

HOME BLOOD GLUCOSE MONITORS (BGM)

To be eligible for coverage of home blood glucose monitors and related accessories and supplies, the beneficiary must meet both of the following basic criteria (1)-(2):

1. The beneficiary has diabetes (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,

2. The beneficiary's treating practitioner has concluded that the beneficiary (or the beneficiary's caregiver) has sufficient training using the particular device prescribed as evidenced by providing a prescription for the appropriate supplies and frequency of blood glucose testing.

For all glucose monitors and related accessories and supplies, if the basic coverage criteria (1)-(2) are not met, the item(s) will be denied as not reasonable and necessary.

Home blood glucose monitors with special features (HCPCS codes E2100, E2101) are covered when the basic coverage criteria (1)-(2) are met and the treating practitioner certifies that the beneficiary has a severe visual impairment (i.e., best corrected visual acuity of 20/200 or worse in both eyes) 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)-(2) are met and the treating practitioner certifies that the beneficiary has an impairment of manual dexterity severe enough to require the use of this special monitoring system. Coverage of code E2101 for beneficiaries with manual dexterity impairments is not dependent upon a visual impairment.

If a glucose monitor (code E2100 or E2101) is provided and basic coverage criteria (1)-(2) plus the additional criteria stated above are not met, it will be denied as not reasonable and necessary.

Lancets (code A4259), blood glucose test reagent strips (code A4253), glucose control solutions (code A4256) and spring powered devices for lancets (code A4258) are covered for beneficiaries for whom the glucose monitor is covered.

More than one spring powered device (code A4258) per 6 months is not reasonable and necessary.

The medical necessity for a laser skin piercing device (code E0620) and related lens shield cartridge (code A4257) has not been established; therefore, claims for code E0620 and/or code A4257 will be denied as not reasonable and necessary.

The quantity of test strips (code A4253) and lancets (code A4259) that are covered depends on the usual medical needs of the beneficiary and whether or not the beneficiary is being treated with insulin, regardless of their diagnostic classification as having Type 1 or Type 2 diabetes mellitus. Coverage of testing supplies is based on the following guidelines:

Usual Utilization

For a beneficiary who is not currently being treated with insulin administrations, up to 100 test strips and up to 100 lancets every 3 months are covered if the basic coverage criteria (1)-(2) (above) are met.

For a beneficiary who is currently being treated with insulin administrations, up to 300 test strips and up to 300 lancets every 3 months are covered if basic coverage criteria (1)-(2) (above) are met.

High Utilization

For a beneficiary who is not currently being treated with insulin administrations, more than 100 test strips and more than 100 lancets every 3 months are covered if criteria (a)–(c) below are met.

For a beneficiary who is currently being treated with insulin administrations, more than 300 test strips and more than 300 lancets every 3 months are covered if criteria (a)–(c) below are met.

a. Basic coverage criteria (1)-(2) listed above for all home glucose monitors and related accessories and supplies are met; and,

b. Within the six (6) months prior to ordering quantities of strips and lancets that exceed the utilization guidelines, the treating practitioner has had an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and their need for the specific quantity of supplies that exceeds the usual utilization amounts described above; and,

c. Every six (6) months, for continued dispensing of quantities of testing supplies that exceed the usual utilization amounts, the treating practitioner must verify adherence to the high utilization testing regimen.

If neither basic coverage criterion (1) or (2) is met, all testing supplies will be denied as not reasonable and necessary. If quantities of test strips or lancets that exceed the utilization guidelines are provided and criteria (a)–(c) are not met, the amount in excess will be denied as not reasonable and necessary.

CONTINUOUS GLUCOSE MONITORS (CGMs)

A non-adjunctive CGM can be used to make treatment decisions without the need for a stand-alone BGM to confirm testing results. An adjunctive CGM requires the user verify their glucose levels or trends displayed on a CGM with a BGM prior to making treatment decisions. On February 28, 2022, CMS determined that both non-adjunctive and adjunctive CGMs may be classified as DME.

Refer to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES and CODING GUIDELINES sections in the LCD-related Policy Article for additional information regarding classification of CGMs as DME.

To be eligible for coverage of a CGM and related supplies, the beneficiary must meet all of the following initial coverage criteria (1)-(5):

1. The beneficiary has diabetes mellitus (Refer to the ICD-10 code list in the LCD-related Policy Article for applicable diagnoses); and,
2. The beneficiary's treating practitioner has concluded that the beneficiary (or beneficiary's caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription; and,
3. The CGM is prescribed in accordance with its FDA indications for use; and,
4. The beneficiary for whom a CGM is being prescribed, to improve glycemic control, meets at least one of the criteria below:
    A. The beneficiary is insulin-treated; or,
    B. The beneficiary has a history of problematic hypoglycemia with documentation of at least one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article (A52464)):
        - Recurrent (more than one) level 2 hypoglycemic events (glucose <54mg/dL (3.0mmol/L)) that persist despite multiple (more than one) attempts to adjust medication(s) and/or modify the diabetes treatment plan; or,
        - A history of one level 3 hypoglycemic event (glucose <54mg/dL (3.0mmol/L)) characterized by altered mental and/or physical state requiring third-party assistance for treatment of hypoglycemia
5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person or Medicare-approved telehealth visit with the beneficiary to evaluate their diabetes control and determined that criteria (1)-(4) above are met.

CGM Continued Coverage

Every six (6) months following the initial prescription of the CGM, the treating practitioner conducts an in-person or Medicare-approved telehealth visit with the beneficiary to document adherence to their CGM regimen and diabetes treatment plan.

When a CGM (code E2102 or E2103) is covered, the related supply allowance (code A4238 or A4239) is also covered. Supplies (code A4238) for an adjunctive CGM integrated into an external insulin infusion pump are covered when the beneficiary meets both the CGM coverage criteria and the coverage criteria for an external insulin infusion pump. Refer to the External Infusion Pumps LCD (L33794) for additional information regarding billing a CGM receiver incorporated into an insulin infusion pump.

If any of the initial coverage criteria (1)-(5), or the continued coverage criterion are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

The supply allowance (code A4238 or A4239) is a monthly allowance that may be billed up to a maximum of three (3) units of service (UOS) per ninety (90) days at a time. Billing more than three (3) UOS per ninety (90) days of code A4238 or A4239 will be denied as not reasonable and necessary. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional billing instructions.

Non-adjunctive CGM devices replace standard home BGMs (HCPCS codes E0607, E2100, E2101) and related supplies (HCPCS codes A4233, A4234, A4235, A4236, A4244, A4245, A4246, A4247, A4250, A4253, A4255, A4256, A4257, A4258, A4259). Claims for a BGM and related supplies, billed in addition to a non-adjunctive CGM device (code E2103) and associated supply allowance (code A4239), will be denied.

Adjunctive CGM devices do not replace a standard home BGM. The supply allowance for an adjunctive CGM (A4238) encompasses all items necessary for the use of the device and includes but is not limited to, CGM sensors and transmitters. Code A4238 does not include a home BGM and related BGM testing supplies. These items may be billed separately, in addition to code A4238. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional information.

All CGM devices billed to Medicare using HCPCS code E2103 must be reviewed for correct coding by the Pricing, Data Analysis and Coding (PDAC) contractor and be listed on the Product Classification List (PCL). Effective July 1, 2022, all CGMs billed to Medicare using HCPCS code E2102 must be reviewed for correct coding by the PDAC contractor and be listed on the PCL. If a CGM system is billed using HCPCS code E2102 or E2103 but the CGM system is not on the PCL for that particular HCPCS code, then the claim will be denied as incorrect coding. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional information.

GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

REFILL REQUIREMENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary, and document an affirmative response, prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are expected to end, and to confirm any changes or modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee and document an affirmative response, prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request and an affirmative response from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the treating practitioner that any changed or atypical utilization is warranted.

Regardless of utilization, a supplier must not dispense more than a three (3) month quantity of BGM testing supplies at a time.

Refill requirements do not apply to code A4238 or A4239. The supply allowance (code A4238 or A4239) is a monthly allowance that may be billed to the DME MACs up to a maximum of three (3) units of service (UOS) and no more than a ninety (90) day supply may be dispensed to the beneficiary at a time. Refer to the CODING GUIDELINES section in the LCD-related Policy Article for additional billing instructions.

Summary of Evidence

N/A

Analysis of Evidence (Rationale for Determination)

N/A

Coding Information

CPT/HCPCS Codes

Group 1 (8 Codes)

Group 1 Paragraph

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

HCPCS MODIFIERS

CG - Policy criteria applied

EY - No physician or other licensed health care provider order for this item or service

KF - Item designated by FDA as Class III device

KS - Glucose monitor supply for diabetic beneficiary not treated by insulin

KX - Requirements specified in the medical policy have been met

HCPCS

EQUIPMENT

Group 1 Codes

Code	Description
E0607	HOME BLOOD GLUCOSE MONITOR
E0620	SKIN PIERCING DEVICE FOR COLLECTION OF CAPILLARY BLOOD, LASER, EACH
E1399	DURABLE MEDICAL EQUIPMENT, MISCELLANEOUS
E2100	BLOOD GLUCOSE MONITOR WITH INTEGRATED VOICE SYNTHESIZER
E2101	BLOOD GLUCOSE MONITOR WITH INTEGRATED LANCING/BLOOD SAMPLE
E2102	ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR OR RECEIVER
E2103	NON-ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR OR RECEIVER
E2104	HOME BLOOD GLUCOSE MONITOR FOR USE WITH INTEGRATED LANCING/BLOOD SAMPLE TESTING CARTRIDGE

Group 2 (23 Codes)

Group 2 Paragraph

ACCESSORIES/SUPPLIES

Group 2 Codes

Code	Description
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
A4238	SUPPLY ALLOWANCE FOR ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE
A4239	SUPPLY ALLOWANCE FOR NON-ADJUNCTIVE, NON-IMPLANTED CONTINUOUS GLUCOSE MONITOR (CGM), INCLUDES ALL SUPPLIES AND ACCESSORIES, 1 MONTH SUPPLY = 1 UNIT OF SERVICE
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
A4271	INTEGRATED LANCING AND BLOOD SAMPLE TESTING CARTRIDGES FOR HOME BLOOD GLUCOSE MONITOR, PER 50 TESTS
A9275	HOME GLUCOSE DISPOSABLE MONITOR, INCLUDES TEST STRIPS
A9276	SENSOR; INVASIVE (E.G., SUBCUTANEOUS), DISPOSABLE, FOR USE WITH NON-DURABLE MEDICAL EQUIPMENT INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY

Code	Description
A9277	TRANSMITTER; EXTERNAL, FOR USE WITH NON-DURABLE MEDICAL EQUIPMENT INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
A9278	RECEIVER (MONITOR); EXTERNAL, FOR USE WITH NON-DURABLE MEDICAL EQUIPMENT INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM
A9999	MISCELLANEOUS DME SUPPLY OR ACCESSORY, NOT OTHERWISE SPECIFIED

General Information

Associated 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." It is expected that the beneficiary's medical records will reflect the need for the care provided. The beneficiary's medical records include the treating practitioner'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 upon request.

GENERAL DOCUMENTATION REQUIREMENTS

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- SWO
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

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

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

Appendices

Insulin does not exist in an oral form and therefore beneficiaries 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 in both eyes.

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

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 Coverage Indications, Limitations and/or Medical Necessity

Sources of Information
Reserved for future use.

Bibliography
N/A

Revision History Information

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
10/01/2024	R16	Revision Effective Date: 10/01/2024 HCPCS CODES: Revised: Long descriptor for HCPCS code A4271 in Group 2 Codes *10/17/2024: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.*	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes
04/01/2024	R15	Revision Effective Date: 04/01/2024 HCPCS CODES: Added: Codes E2104 to Group 1 Codes and A4271 to Group 2 Codes *05/02/2024: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates per CMS HCPCS coding determinations.*	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2024	R14	Revision Effective Date: 01/01/2024 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: “and document an affirmative response” to language that pertains to contact with the beneficiary or caregiver/designee for DMEPOS products supplied as refills Revised: “approaching exhaustion” to “expected to end” in regard to existing supplies Revised: “Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date.” to “Contact with the beneficiary or designee regarding refills must take place no sooner than 30 calendar days prior to the expected end of the current supply.” Revised: “For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product.” to “For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the expected end of the current supply.” *12/14/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because the revisions are non-discretionary updates to refill requirement information per CMS Final Rule CMS-1780-F.*	• Provider Education/Guidance • Other (CMS Final Rule CMS-1780-F)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2024	R13	Revision Effective Date: 01/01/2024 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Added: “or Medicare-approved telehealth” to High Utilization coverage criteria Removed: One (1) unit of service (UOS) per thirty (30) days regarding billing for supply allowance code A4238 or A4239 Added: Three (3) UOS per ninety (90) days regarding billing for supply allowance code A4238 or A4239 and “Billing more than three (3) UOS per ninety (90) days of code A4238 or A4239 will be denied as not reasonable and necessary.” SUMMARY OF EVIDENCE: Removed: Summary of evidence information, due to not being applicable to the non-discretionary changes ANALYSIS OF EVIDENCE (RATIONALE FOR DETERMINATION): Removed: Analysis of evidence information, due to not being applicable to the non-discretionary changes BIBLIOGRAPHY: Removed: Bibliography information, due to not being applicable to the non-discretionary changes *11/09/2023: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary.*	• Provider Education/Guidance • Other (CMS direction)

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
04/16/2023	R12	Revision Effective Date: 04/16/2023 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Revised: Coverage criteria to separate initial coverage and continued coverage requirements Removed: “with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump” from CGM coverage criterion pertaining to beneficiary being insulin-treated Added: “The beneficiary’s treating practitioner has concluded that the beneficiary (or beneficiary’s caregiver) has sufficient training using the CGM prescribed as evidenced by providing a prescription” as a CGM initial coverage criterion Removed: “The beneficiary is insulin-treated with multiple (three or more) daily administrations of insulin or a continuous subcutaneous insulin infusion (CSII) pump” from CGM coverage criteria Removed: “The beneficiary’s insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results” from CGM coverage criteria Revised: Initial coverage criterion language pertaining to the in-person visit, to clarify that the visit may also be a “Medicare-approved telehealth visit” Revised: Initial coverage CGM criterion language pertaining to the in-person visit, to change notation of “criteria (1-3) above” to “criteria (1)-(4) above” Added: Initial coverage CGM criterion pertaining to history of problematic hypoglycemia Revised: Continued coverage CGM criterion language pertaining to the in-person visit, to clarify that the visit may also be a “Medicare-approved telehealth visit” and that the practitioner must “document” adherence to the CGM regimen and diabetes treatment plan Removed: “K0554” and “K0553” from reference to a non-adjunctive CGM device and associated supply allowance (respectively) Added: “E2103” and “A4239” in reference to a non-adjunctive CGM device and associated supply allowance (respectively) SUMMARY OF EVIDENCE: Added: Information related to the modified coverage criteria for CGM ANALYSIS OF EVIDENCE: Added: Information related to the modified coverage criteria for CGM BIBLIOGRAPHY: Added: Section related to the modified coverage criteria for CGM RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments (A59330)	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes • Reconsideration Request

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2023	R11	Revision Effective Date: 01/01/2023 CONTINUOUS GLUCOSE MONITORS (CGM): Removed: Statement regarding general CGM term referring to both therapeutic/non-adjunctive and non-therapeutic/adjunctive Removed: “therapeutic” and “non-therapeutic” Removed: HCPCS codes K0554 and K0553 Added: HCPCS codes E2103 and A4239 REFILL REQUIREMENTS: Removed: HCPCS code K0553 Added: HCPCS code A4239 HCPCS CODES: Revised: Long descriptor for HCPCS code E2102 in Group 1 Codes Added: HCPCS code E2103 to Group 1 Codes Removed: HCPCS code K0554 from Group 1 Codes Revised: Long descriptor for HCPCS code A4238 in Group 2 Codes Added: HCPCS codes A4239, A9277, A9276 and A9278 to Group 2 Codes Removed: HCPCS codes A9279 and K0553 from Group 2 codes *12/29/2022: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary updates to CMS HCPCS coding determinations.*	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes
02/28/2022	R10	Revision Effective Date: 02/28/2022 HCPCS CODES: Revised: Location of E2102 information, moving the information from Group 1 Paragraph text to Group 1 Codes HCPCS list (code remains effective for dates of service on or after 04/01/2022) Revised: Location of A4238 information, moving the information from Group 2 Paragraph text to Group 2 Codes HCPCS list (code remains effective for dates of service on or after 04/01/2022) *04/28/2022: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary updates to CMS HCPCS coding determinations.*	• Provider Education/Guidance

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
02/28/2022	R9	Revision Effective Date: 02/28/2022 CMS NATIONAL COVERAGE POLICY: Removed: “CMS Ruling 1682R” COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Removed: Reference to CMS Ruling 1682R Added: CGM refers to both therapeutic/nonadjunctive and non-therapeutic/adjunctive CGMs Added: Language describing “therapeutic,” “non-adjunctive,” “non-therapeutic,” and “adjunctive” terms and term usage Added: Information regarding classification of CGMs as DME Revised: Coverage information to include reference to adjunctive CGM (E2102) and related supply allowance (A4238) Added: Statement referring to External Infusion Pumps LCD for information regarding billing of CGM receiver functionality integrated into external insulin infusion pump Added: “Adjunctive CGM devices do not replace a standard home BGM” Added: HCPCS code A4238 does not include a home BGM and related BGM testing supplies Added: Reference to coding verification review requirement for HCPCS code E2102 (effective July 1, 2022) Clarified: No more than a 90-day supply of CGM supplies may be dispensed at a time Revised: “Refill requirements do not apply to code K0553” to “Refill requirements do not apply to code K0553 or A4238” SUMMARY OF EVIDENCE: Removed: Summary of evidence information, due to not being applicable to the non-discretionary changes ANALYSIS OF EVIDENCE: Removed: Analysis of evidence information, due to not being applicable to the non-discretionary changes HCPCS CODES: Added: HCPCS code E2102 to Group 1 Codes (information located in Group 1 Paragraph text) – code effective 04/01/2022 Added: HCPCS code E1399 to Group 1 Codes Added: HCPCS code A4238 to Group 2 Codes (information located in Group 2 Paragraph text) – code effective 04/01/2022 Added: HCPCS codes A9279 and A9999 to Group 2 Codes Removed: HCPCS codes A9276, A9277, and A9278 from Group 2 Codes	• Provider Education/Guidance • Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
		BIBLIOGRAPHY: Removed: Bibliography information, due to not being applicable to the non-discretionary changes *03/24/2022: Pursuant to the 21st Century Cures Act, these revisions do not require notice and comment because they are non-discretionary.*	
07/18/2021	R8	Revision Effective Date: 07/18/2021 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Four times or more per day testing with blood glucose monitor as prerequisite for CGM coverage Revised: “injections” to “administrations” for insulin treatment regimen criterion for CGMs Removed: “Medicare-covered” from CSII pump criterion language for CGMs Clarified: Coding verification language for products billed as K0554 SUMMARY OF EVIDENCE: Added: Information related to glucose testing and insulin administration Revised: “5” to “1” minutes for measuring of interstitial fluid glucose content by CGM device ANALYSIS OF EVIDENCE: Added: Information related to glucose testing and insulin administration APPENDICES: Revised: Language of insulin-treated, by removing reference to insulin injections BIBLIOGRAPHY: Added: Section related to glucose testing and insulin administration RELATED LOCAL COVERAGE DOCUMENTS: Added: Response to Comments (A58798)	• Provider Education/Guidance • Reconsideration Request

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2020	R7	Revision Effective Date: 01/01/2020 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Statement to refer to ICD-10 Codes that are Covered section in the LCD-related PA Added: Statement to refer to ICD-10 code list in the LCD-related Policy Article Revised: “physician” to “treating practitioner” Revised: "treating physician" to "treating practitioner" Revised: “month” to “30 days,” as clarification of billing K0553 Revised: Format of HCPCS code references, from code spans to individually-listed HCPCS Revised: Order information as a result of Final Rule 1713 REFILL REQUIREMENTS: Revised: “ordering physician” to “treating practitioner” CODING INFORMATION: Removed: Field titled “Bill Type” Removed: Field titled “Revenue Codes” Removed: Field titled “ICD-10 Codes that Support Medical Necessity” Removed: Field titled “ICD-10 Codes that DO NOT Support Medical Necessity” Removed: Field titled “Additional ICD-10 Information” GENERAL DOCUMENTATION REQUIREMENTS: Revised: Prescriptions (orders) to SWO APPENDICES: Revised: “physician” to “practitioner” *02/20/2020: Pursuant to the 21st Century Cures Act , these revisions do not require notice and comment because they are due to non-discretionary coverage updates reflective of CMS FR-1713, HCPCS code changes, and non-substantive corrections (listing individual HCPCS codes instead of a HCPCS code-span).*	• Provider Education/Guidance • Other

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/01/2019	R6	Revision Effective Date:01/01/2019 COVERAGE INDICATIONS, LIMITATIONS, AND/OR MEDICAL NECESSITY: Removed: Statement to refer to diagnosis code section below Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY: Moved: Statement about noncovered diagnosis codes moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction	• Other (ICD-10 code relocation per CMS instruction)
01/12/2017	R5	Revision Effective Date: 01/12/2017 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: CPT/HCPCS Codes: Revised: Incorporated K0554 into Group 1 Codes and HCPCS code K0553 into Group 2 Codes *04/19/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.*	• Revisions Due To CPT/HCPCS Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
01/12/2017	R4	Revision Effective Date: 01/12/2017 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and Directions to Standard Documentation Requirements Revised: Coverage criteria for home blood glucose monitors Added: Documentation requirements for home blood glucose monitors Added: Coverage criteria for continuous glucose monitors and supply allowance Added: Documentation requirements for continuous glucose monitors Added: General Requirements Revised: Refill requirements Added: HCPCS codes for therapeutic CGM (K0554) and supply allowance (K0553) out of sequence to allow early publishing of codes and narratives. (For dates of service on or after 07/01/2017) DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Directions to Standard Documentation Requirements Removed: PIM reference under Appendices RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	• Provider Education/Guidance • Other (Revisions and updates based on CMS Ruling 1682R)
10/01/2016	R3	Revision Effective Date 10/01/2016 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation language - ACA order requirements – Effective 04/28/16 ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY: Added: New ICD-10 codes Deleted: Non-valid ICD-10 Revised: ICD-10 code descriptions DOCUMENTATION REQUIREMENTS: Revised: Standard documentation language for orders, added New order requirements, and Correct coding instructions; revised Proof of delivery instructions – Effective 04/28/16	• Provider Education/Guidance • Revisions Due To ICD-10-CM Code Changes

Revision History Date	Revision History Number	Revision History Explanation	Reasons for Change
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	• Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	Revision Effective Date: 10/31/2014 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD Added: Instructions for Equipment Retained from a Prior Payer Revised: Repair to beneficiary-owned DMEPOS	• Provider Education/Guidance

Associated Documents

Attachments

N/A

Related Local Coverage Documents

Articles

A52464 - Glucose Monitor - Policy Article

A59330 - Response to Comments: Glucose Monitors – DL33822

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents

NCDs

280.1 - Durable Medical Equipment Reference List

40.2 - Home Blood Glucose Monitors

Public Versions

Updated On	Effective Dates	Status	
10/09/2024	10/01/2024 - N/A	Currently in Effect	You are here
04/25/2024	04/01/2024 - 09/30/2024	Superseded	View

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Keywords

N/A