

09-E0000-14

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Subject: Blood Glucose Monitors and Supplies

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

Diabetes mellitus (DM) is a disease characterized by hyperglycemia resulting from abnormal insulin secretion and/or abnormal insulin action within the body. Diabetes is diagnosed and monitored by routine testing of blood glucose levels. Self-management of diabetes is essential for the control of the disease and curtailing irreversible dysfunction and possible failure of multiple body systems.

Blood glucose monitors (glucometers) are portable battery-powered devices used to determine the blood glucose level by exposing a reagent strip to a small blood sample. The user inserts a reagent strip into the monitor and uses a disposable lancet to draw a drop of blood to place on the reagent strip. The monitor provides a direct readout of the blood glucose level.

Glucometers designed specifically for use by individuals with visual impairments or impairment of manual dexterity are similar to standard blood glucose monitors in terms of reliability and sensitivity. They differ from standard monitors by having features such as voice synthesizers, automatic timers, and specially designed arrangements of supplies and materials to enable these individuals to use the equipment without assistance.

POSITION STATEMENT:

Home blood glucose monitors **meet the definition of medical necessity** when **ALL** of the following conditions are met:

- The member is being treated for diabetes; **AND**
- The monitor and accessories have been ordered by the attending physician who is treating the diabetes and maintains records of care provided including medical necessity of the ordered testing frequency; **AND**

- The member is capable of being trained in the use of the device or a responsible caregiver can be trained in the use of the device and in monitoring the member; **AND**
- The device is designed for home use

In addition, home blood glucose monitors with special features (E2100, E2101, E2104) **meet the definition of medical necessity** when:

- The member's physician documents a severe visual impairment that prevents the use of a standard blood glucose monitor and requires the use of a special monitoring device (severe visual impairment defined as best corrected visual acuity is 20/200 or worse)

NOTE: E2101 may also **meet the definition of medical necessity** for individuals with impairment in manual dexterity when the above criteria is met, and the physician certifies that the member has an impairment of manual dexterity that is severe enough to require the use of this special monitoring device. Documentation submitted by the physician must include the exact nature of the physical impairment. Also, coverage of E2101 for those with manual dexterity impairments is not dependent upon a visual impairment.

Accessories and supplies used in conjunction with these devices **meet the definition of medical necessity** if the device **meets the definition of medical necessity**.

Blood glucose monitoring devices with special features **do not meet the definition of medical necessity** when the above criteria are not met.

The following supplies **do not meet the definition of medical necessity** and are **non-covered**:

1. Laser skin piercing devices used in place of spring powered devices for lancets
2. Alcohol or peroxide, betadine or pHisoHex (not required for proper functioning of the device)

NOTE: The written dispensing order (written, faxed, or verbal order followed by a written order) must be received from a physician or provider licensed to treat diabetes mellitus and must be obtained prior to dispensing a blood glucose monitor and/or supplies. The dispensing order should be updated no less than once per year. The supplier must maintain a copy of the dispensing order. The detailed written order must contain all of the following:

1. All item(s) to be dispensed
2. The specific frequency of testing based on the member's medical condition
3. The treating physician's signature, including the date
4. A start date of the order – only required if the start date is different than the signature date
5. The specific diagnosis (insulin or non-insulin dependent)

Replacement of a functioning blood glucose monitor for any purpose, including upgrading due to changes in technology, **does not meet the definition of medical necessity**.

Blood glucose monitors will be eligible for replacement if the warranty has expired, or the monitor is damaged beyond repair.

Replacement batteries that may be purchased over the counter for use in blood glucose monitors are not specific to the treatment of diabetes and **do not meet the definition of medical necessity** and are therefore **non-covered**.

Software or hardware for the purpose of downloading or storage of data to a computer **does not meet the definition of medical necessity**.

BILLING/CODING INFORMATION:

HCPCS Coding:

Blood Glucose Monitors:

E0607	Blood glucose monitor
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Blood Glucose Monitors with special features:

E2100	Blood glucose monitor with integrated voice synthesizer
E2101	Blood glucose monitor with integrated lancing/blood sample
E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge

Supplies:

A4233	Replacement battery, alkaline (other than J cell), for use with medically necessary home blood glucose monitor owned by patient, each (non-covered)
A4234	Replacement battery, alkaline, J cell, for use with medically necessary home blood glucose monitor owned by patient, each (non-covered)
A4235	Replacement battery, lithium, for use with medically necessary home blood glucose monitor owned by patient, each (non-covered)
A4236	Replacement battery, silver oxide, for use with medically necessary home blood glucose monitor owned by patient, each (non-covered)
A4245	Alcohol wipes, per box
A4253	Blood glucose test or reagent strips for home blood glucose monitor, per 50 strips
A4256	Normal, low, high calibrator solution/chips
A4257	Replacement lens shield cartridge for use with laser skin piercing device, each (non-covered)
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
E0620	Skin piercing device for collection of capillary blood, laser, each (non-covered)

REIMBURSEMENT INFORMATION:

Refer also to sections entitled **POSITION STATEMENT**.

Reimbursement for covered accessories and supplies used in conjunction with home blood glucose monitors (with or without special features) is limited to the following:

Non-Insulin dependent Diabetes Mellitus:

HCPCS code **A4253** (test/reagent strips) is limited to quantities of **2 units per 3-month period (1 unit equals 50 strips)** when dispensed for treatment of non-insulin dependent diabetes mellitus.

HCPCS code **A4259** (lancets, per box of 100) is limited to quantities of **1 unit per 3-month period (1 unit equals 100 lancets)** when dispensed for treatment of non-insulin dependent diabetes mellitus.

Insulin Dependent Diabetes Mellitus:

HCPCS code **A4253** (test/reagent strips) is limited to quantities of **6 to 8 units per 3-month period (1 unit equals 50 strips)** when dispensed for treatment of insulin dependent diabetes mellitus.

HCPCS code **A4259** (lancets, per box of 100) is limited to quantities of **3 to 4 units per 3-month period (1 unit equals 100 lancets)** when dispensed for treatment of insulin dependent diabetes mellitus.

Insulin Pump Therapy:

HCPCS code **A4253** (test/reagent strips) is limited to quantities of **8 to 18 units per 3-month period (1 unit equals 50 strips)** when dispensed for treatment of insulin dependent diabetes mellitus treated with insulin pump therapy.

HCPCS code **A4259** (lancets, per box of 100) is limited to quantities **4 to 9 units per 3-month period (1 unit equals 100 lancets)** when dispensed for treatment of insulin dependent diabetes mellitus treated with insulin pump therapy.

Additional Supplies:

HCPCS code **A4256** (Glucose control solutions (Calibrator solution/chips)) is limited to a quantity of **4 per year** when dispensed for treatment of diabetes mellitus.

HCPCS code **A4258** (Spring powered devices for lancets) is limited to a quantity of **2 per year** when dispensed for treatment of diabetes mellitus.

HCPCS code **E0607** (Blood glucose monitors) is limited to a quantity of **1 every 3 years** when dispensed for treatment of diabetes mellitus.

NOTE: Florida Blue will cover quantities in excess of these amounts with appropriate documentation of **medical necessity**. Additional quantities of these supplies will be covered if the treating physician has ordered a frequency of testing that exceeds the utilization guidelines and has documented the specific reason for the additional testing in the medical record (e.g., new onset of insulin dependent diabetes).

LOINC Codes:

The following information may be required documentation to support medical necessity: physician history and physical, physician progress notes, treatment plan, and prescription for DME and/or supplies.

Documentation Table	LOINC Codes	LOINC Time Frame Modifier Code	LOINC Time Frame Modifier Codes Narrative
Physician history and physical	28626-0	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim
Attending physician visit note	18733-6	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Treatment plan	18776-5	18805-2	Include all data of the selected type that represents observations made six months or fewer before starting date of service for the claim.
Prescription for medical equipment or product	57829-4	18807-8	Include all data of the selected type that represents observations made one year or less before starting date of service for the claim.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

The following National Coverage Determinations (NCDs) were reviewed on the last guideline reviewed date: Blood Glucose Testing (190.20), and Home Blood Glucose Monitors (40.2), located at cms.gov.

The following Local Coverage Determination (LCD) was reviewed on the last guideline reviewed date: Glucose Monitors (L33822) located at cms.gov.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

External Insulin Infusion Pumps and Continuous Glucose Monitors, 01-99000-03

OTHER:

Florida statute 641.31 Health maintenance contracts

(26)(a) Each health maintenance organization and prepaid health plan shall provide coverage for all medically appropriate and necessary equipment, supplies, and services used to treat diabetes, including outpatient self-management training and educational services, if the patient's primary care physician, or the physician to whom the patient has been referred who specializes in treating diabetes, certifies that the equipment, supplies, or services are necessary.

REFERENCES:

1. Agency for Healthcare Research & Quality. Technology Assessment: Applicability of the Evidence Regarding Intensive Glycemic Control and Self-Monitored Blood Glucose to Medicare Patients with Type 2 Diabetes. September 10, 2007.
2. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse Guideline Summary NGC-7374: Gestational diabetes mellitus (GDM). Evidence-based nutrition practice guideline. American Dietetic Association (ADA); 2008.
3. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse Guideline Summary NGC-8116: VA/DoD clinical practice guideline for the management of diabetes mellitus. Department of Veteran Affairs, Department of Defense; 2010 Aug.
4. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse Guideline Summary NGC-8904: Diabetes management at camps for children with diabetes. American Diabetes Association. Diabetes Care 2012 Jan;35(Suppl 1): S72-5.
5. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse Guideline Summary NGC-8917: Standards of medical care in diabetes. IX. Diabetes care in specific settings. American Diabetes Association. Diabetes Care 2011 Jan;34(Suppl 1): S43-6.
6. Agency for Healthcare Research and Quality (AHRQ). National Guideline Clearinghouse Guideline Summary NGC-9095: Diagnosis and management of type 2 diabetes mellitus in adults. Institute for Clinical Systems Improvement (ICSI); 2010 Jul.
7. American Association of Diabetes Educators (AADE) Position Statement: AADE 7™ Self-Care Behaviors. 2011.
8. American Diabetes Association. Standards of Medical Care in Diabetes – 2008. Diabetes Care, Vol 31 supplement 1, January 2008.
9. American Diabetes Association. Standards of Medical Care in Diabetes – 2009. Diabetes Care, Volume 32, supplement 1, 2009.
10. Blue Cross Blue Shield Association Evidence Positioning System®. 1.01.03 - Blood Glucose Monitors (Glucometers) (Archived 05/11).
11. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) L11520 Glucose Monitors (Archived 09/30/15).
12. Centers for Medicare and Medicaid Services (CMS). Local Coverage Determination (LCD) L33822 Glucose Monitors (10/01/15) (Revised 04/16/23).
13. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) 40.2 Home Blood Glucose Monitors (06/19/06).
14. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) 190.2 Blood Glucose Testing (01/01/05).
15. Cohen L, et al. American Association of Diabetes Educators Position Statement: Diabetic Kidney Disease. 2009.
16. ElSayed NA, Aleppo G, Aroda VR, Bannuru RR, Brown FM, Bruemmer D, Collins BS, Hilliard ME, Isaacs D, Johnson EL, Kahan S, Khunti K, Leon J, Lyons SK, Perry ML, Prahalad P, Pratley RE,

Seley JJ, Stanton RC, Gabbay RA, on behalf of the American Diabetes Association. 7. Diabetes Technology: Standards of Care in Diabetes-2023. Diabetes Care. 2023 Jan 1;46(Suppl 1): S111-S127. doi: 10.2337/dc23-S007.

17. Florida Statue 627.6408 Diabetes treatment services.
18. Florida Statue 641.31 health maintenance contracts.
19. Guerci B, et al. Measuring Capillary Blood Ketones by Fingerstick Samples During Metabolic Deterioration After Continuous Subcutaneous Insulin Infusion Interruption in Type 1 Diabetic Patients. Diabetes Care 26:1137–1141, 2003.
20. Handelsman Y, et al. American College of Clinical Endocrinologists Medical Guidelines for Clinical Practice for Developing a Diabetes Mellitus Comprehensive Care Plan. Endocrine Practice Volume 17 (Suppl 2) March/April 2011.
21. National Institute of Health and Care Excellence (NICE). NICE Guideline 18 (NG18): Diabetes (type 1 and type 2) in children and young people: diagnosis and management [Updated May 2023]. Accessed at <https://www.nice.org.uk/guidance/ng18/chapter/Recommendations>.
22. National Institute of Health and Care Excellence (NICE). NICE Guideline 28 (NG28): Type 2 diabetes in adults: management [Updated June 2022]. Accessed at <https://www.nice.org.uk/guidance/ng28/chapter/Recommendations>.
23. Rodbard HW, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An Algorithm for Glycemic Control. Endocrine Practice 2009; 15 (No. 6).
24. UpToDate. Glucose monitoring in the management of nonpregnant adults with diabetes mellitus. 2021. Accessed at uptodate.com.
25. UpToDate. Glucose monitoring in the ambulatory management of nonpregnant adults with diabetes mellitus. 2023. Accessed at uptodate.com.
26. Yuan Y, Zhou X, Jia W, Zhou J, Zhang F, Du J, Ji L. The association between self-monitoring of blood glucose and HbA1c in type 2 diabetes. Front Endocrinol (Lausanne). 2023 Feb 7; 14:1056828. doi: 10.3389/fendo.2023.1056828.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/28/23.

GUIDELINE UPDATE INFORMATION:

12/15/02	Medical Coverage Guideline Reformatted and Revised.
04/15/03	Revised to clarify reimbursement information for supplies used with blood glucose monitors, with or without special features.
10/15/04	Scheduled review; no change in coverage statement.
02/15/06	HCPCS coding update: remove A4254; add A4233 – A4236. Revision consisting of removal of the limitation for test/reagent strips and lancets.
07/15/06	Revisions consisting of adding Florida statute language and non-coverage statement regarding over-the-counter replacement batteries.
04/20/09	Revision with updated references. Add Medicare Advantage information.

08/15/09	Revision to add information to the position statement regarding dispensing orders. Update reimbursement section for supplies. Updated Medicare Advantage exception. Add ICD 9 codes for gestational diabetes to diagnoses that support medical necessity.
06/15/10	Revise reimbursement statement by adding limit for A4253 and A4259 for treatment with insulin pump therapy; add requirement for Certificate of Medical Necessity with link to the form.
10/15/10	Revision: related ICD-10 codes added.
11/15/10	Revision: guideline reformatted.
09/15/11	Revision: formatting changes.
02/15/13	Unscheduled review. Revised description. Revised position statement (urine reagent strips/tablets are eligible for coverage). Updated references.
05/11/14	Revision: Program Exceptions section updated.
11/01/15	Revision: ICD-9 Codes deleted.
10/01/16	Revision: Billing/Coding Information section updated.
11/15/19	Scheduled review. Position statement maintained. Revised program exception section, Updated references.
07/15/20	Revision: Deleted non-covered designation for code A4245.
11/15/21	Scheduled review. Maintained position statement and updated references.
10/15/23	Scheduled review. Maintained position statement and updated references.
04/01/24	Quarterly CPT/HCPCS coding update. Added A4271, E2104.
10/01/24	Quarterly CPT/HCPCS coding update. Revised A4271.