Blood Glucose Monitors and Supplies

MEDICAL POLICY NUMBER: 239

Effective Date: 1/1/2025

Last Review Date: 10/2024

Next Annual Review: 8/2025

INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance and Providence Plan Partners as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☐ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

Blood Glucose Monitor and Supplies: Ancillary Guideline Note A2, Guideline Note 108

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

I. Home blood glucose monitors and related accessories and supplies (i.e., lancets [A4259], glucose control solutions [A4256], and spring powered devices for lancets [A4258]), may be considered **medically necessary** when **both** of the following criteria are met (A.-B.):

   A. The member has been diagnosed with diabetes; **and**
   B. The member's treating practitioner has concluded that the member (or the member'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.

II. Home glucose monitors and related accessories and supplies are considered **not medically necessary** if the coverage criteria (see Criterion I) are not met.

III. Home blood glucose monitors with special features (E2100, E2101) may be medically necessary for individuals with a visual impairment when **both** of the following are met A.-B.):

   A. The coverage criteria (See Criterion I) are met; **and**
   B. 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.

IV. Home blood glucose monitors represented by HCPCS code E2101 may also be **medically necessary** for those with impairment of manual dexterity when **both** of the following are met (A.-B.):

A. The coverage criteria (see Criterion I) are met; **and**
B. The treating practitioner certifies that the member has **an impairment of manual dexterity** severe enough to require the use of this special monitoring system. (Note, coverage of E2101 for individuals with manual dexterity impairments is not dependent upon the above visual impairment criteria).

V. Blood glucose monitors with special features (code E2100 or E2101) are considered **not medically necessary and not covered when** the above criteria (III and IV) are not met.

VI. More than one spring powered device (A4258) per 6 months is considered **not medically necessary**.

VII. Laser skin piercing devices (E0620) and the related lens shield cartridge (A4257) are considered **not medically necessary.**

VIII. The quantity of lancets (A4259) which may be considered **medically necessary** depends on the following guidelines:

A. Usual Utilization
   1. For a member who is not currently being treated with insulin injections, up to 100 lancets every 3 months are covered if the coverage criteria (see Criterion I) are met
   2. For a member who is currently being treated with insulin injections, up to 300 lancets every 3 months are covered if coverage criteria (Criterion I) are met
B. High Utilization
   1. For a beneficiary who is not currently being treated with insulin injections, more than 100 lancets every 3 months are covered if criteria (a.-c) below are met:
      a. Coverage criteria (Criterion I) 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 lancets that exceed the utilization guidelines, the treating practitioner has had an in-person visit with the member 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.

IX. Quantities of lancets that exceed the utilization guidelines provided or if the above criteria for high utilization (See Criteria VIII.B.1.a-c) are not met, the amount in excess will be considered **not medically necessary.**

Non-Covered Items

X. Alcohol or peroxide (A4244, A4245), betadine or phisoHex (A4246, A4247) are considered **not medically necessary** because these items are not required for the proper functioning of the device.

XI. Urine test reagent strips or tablets (code A4250) are considered **not medically necessary** because they are not used with a glucose monitor.

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

XIII. Glucose monitors that are not designed for use in the home must be coded A9270 and will be denied a noncovered benefit.

XIV. Home blood glucose disposable monitors, including test strips (A9275) are considered **not medically necessary** because these monitors do not meet the definition of DME.

Link to Evidence Summary

POLICY CROSS REFERENCES

- Advanced Diabetes Management Technology, MP27

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

This policy may be primarily based on the following Center for Medicare and Medicaid Services (CMS) guidance:

- Local Coverage Determination (LCD): Glucose Monitors (L33822)[1]; and
- Local Coverage Article (LCA): Glucose Monitor – Policy Article (A52464)[2].

BACKGROUND

Home glucose monitors enable certain patients to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

BILLING GUIDELINES AND CODING

Refills of DMEPOS Items

The following refill guidelines are based on the LCD L33822[1] and the Medicare Program Integrity Manual[3]:

For DMEPOS provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS that are supplied as refills to the original order, suppliers must contact the member prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized to do so by the member. This is to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes or modifications to the order. Contact with the member or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. 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. This is regardless of which delivery method is utilized.

For all DMEPOS items that are provided on a recurring basis, including DMEPOS products that are supplied as refills to the original order, suppliers are required to have contact with the member or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request 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 ordering physicians that any changed or atypical utilization is warranted. Regardless of utilization, a supplier must not dispense more than a three (3)-month quantity at a time.

See Providence Health Plan Pharmacy Operational Policy: *Miscellaneous Products, Blood Glucose Test Strips* regarding glucose test or reagent strips (A4253).

CODES*		
Blood Glucose Monitors		
	E0607	Home blood glucose monitor
	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
Glucose Supplies		
	A4206	Syringe with needle, sterile, 1 cc or less, each
	A4215	Needle, sterile, any size, each

	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
	A4255	Platforms for home blood glucose monitor, 50 per box
	A4256	Normal, low and high calibrator solution / chips
	A4258	Spring-powered device for lancet, each
	A4259	Lancets, per box of 100
	S8490	Insulin syringes (100 syringes, any size)
	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)
	A4257	Replacement lens shield cartridge for use with laser skin piercing device, each
	A4271	Integrated lancing and blood sample testing cartridges for home blood glucose monitor, per 50 tests
	A9270	Non-covered item or service
	A9275	Home glucose disposable monitor, includes test strips
	E0620	Skin piercing device for collection of capillary blood, laser, each

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

REFERENCES

1. Centers for Medicare & Medicaid Services. Local Coverage Article: Glucose Monitor - Policy Article (A52464). Revision Effective Date: 4/1/2024. https://www.cms.gov/medicare-coverage-database/details/article-details.aspx?articleId=52464. Accessed 7/15/2024.
2. Centers for Medicare & Medicaid Services. Local Coverage Determination (LCD): Glucose Monitors (L33822). Revision Effective Date: For services performed on or after 07/18/2021.

https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33822. Accessed 7/5/2022.
3. Centers for Medicare & Medicaid Services. Medicare Program Integrity Manual, Chapter 5, §5.2.6 - Refills of DMEPOS Items Provided on a Recurring Basis https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c05.pdf. Accessed 7/7/2022.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.
9/2023	Annual update. No changes to criteria or codes.
4/2024	Q2 2024 code set update.
10/2024	Annual review. Policy title update. No changes to policy criteria or coding. Q4 2024 code set update- revised code description.
1/2025	Interim update. Coding configuration