Medicare Medical Policy

Diabetes: Blood Glucose Monitor and Supplies

MEDICARE MEDICAL POLICY NUMBER: 276

Effective Date: 4/1/2024

Last Review Date: 3/2024

Next Annual Review: 8/2024

INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. 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.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

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

PRODUCT AND BENEFIT APPLICATION

☒ Medicare Only

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Note: Blood glucose test or reagent strips (A4253) are addressed in the Providence Health Plan Pharmacy policy: *Miscellaneous Products, Blood Glucose Test Strips*. Continuous glucose monitors (CGMs) and related supplies are also addressed in a separate Medicare medical policy. See Policy Cross References below.

Service	Medicare Guidelines
Home Blood Glucose Monitors (BGM) and Related Accessories and Supplies	• National Coverage Determination (NCD): Home Blood Glucose Monitors (40.2) • Local Coverage Determination (LCD): Glucose Monitors (L33822) • Local Coverage Article: Glucose Monitor – Policy Article (A52464)
Replacement of BGMs	Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.2.C. – Replacement Standard Medicare DME replacement rules apply. Primary factors considered will include, but may not be limited to: • Whether the item is being rented or is member owned; • Reason for replacement (e.g., change in medical condition, lost, stolen, worn out, damaged, etc.); • Whether or not the 5 year reasonable useful lifetime (RUL) for the device has been reached; **and** • Whether or not the item is still under manufacturer warranty. See Policy Guidelines below for specific information regarding replacement requests, as well as replacement supplies.

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A).* If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form **cannot** be used for Medicare Advantage members. *(Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)*

POLICY CROSS REFERENCES

- Advanced Diabetes Management Technology, MP25

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

POLICY GUIDELINES

REPLACEMENT REQUESTS

Replacement of Home BGMs

The definition of replacement can be found in the Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services, §110.2.C. – Replacement, and refers to the provision of an identical or nearly identical item.

Replacement can be due to the following scenarios:

- **Irreparable *damage*** refers to a specific accident or to a natural disaster (e.g., fire, flood).
- **Irreparable *wear*** refers to deterioration sustained from day-to-day usage over time and a specific event cannot be identified.

Replacement of BGMs pumps ***prior to*** the 5-year reasonable useful lifetime (RUL) period being reached:

Replacement due to **irreparable *wear***:

- Medicare expects *rented* equipment to remain in good working order for the entire RUL of the equipment. Therefore, if the equipment does not last for the entire 5-year RUL, the supplier must replace the equipment at no charge.
- For member-owned equipment, coverage for replacement equipment is not allowed prior to the 5-year RUL for irreparable ***wear*** per Medicare statute.

Replacement due to **change in patient medical condition**:

- Replacement of rented or member-owned equipment may be warranted if:
- The current item(s) can no longer meet the patient's therapeutic medical needs; **and**
- It is the least costly option to replace the equipment in order to meet the patient's medical needs (rather than repair or reconfigure with available options).

Replacement of BGM pumps ***after*** the 5-year RUL period is reached due to irreparable *wear* ***OR*** replacement ***at any time*** due to *theft, loss,* or irreparable *damage*:

- If the 5-year RUL of the equipment is reached, replacement must still be medically reasonable and necessary:
    - The member must be regularly using the equipment as prescribed; and,
    - The equipment continues to provide the needed therapeutic benefit.
        - For irreparably *worn* devices, documentation must support the current device no longer meets the therapeutic medical needs of the member and cannot be repaired to a state where it can provide the needed therapeutic benefit (e.g., it is not cost effective to repair the current device).

- If an item is still under manufacturer warranty and can be repaired, requests for replacement with a new device will be denied.

- For lost, stolen, or irreparably *damaged* devices, documentation of the specific incident of irreparable damage or a written explanation regarding the loss (e.g., details around circumstances of the loss, a police report for stolen items, etc.).

Replacement of Supplies

Supplies necessary to achieve the therapeutic benefit of the device or to assure the proper functioning of a medically necessary device are also covered. This includes replacement of supplies that are consumable, as well as batteries when no longer functional. Because these items generally require replacement on a frequent basis, they are not subject to the same requirements as other DME replacements (i.e., the 5-year RUL rule will not likely apply); however, utilization may be subject to audit and quantity limits may apply, as found in LCDs or LCAs. Please review the LCDs and LCAs above for any potential frequency limitations on replacement supplies.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

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

Like all S-codes, the *National Physician Fee Schedule Relative Value File (NPFSRVF)*, which is published by Medicare[1], indicates HCPCS code S8490 has been assigned a Status Indicator of "I." This is defined as "Not valid for Medicare purposes." In addition, all S-codes codes, including S8490, are not recognized as valid codes for claim submission as indicated in the relevant Company Coding Policy *(HCPCS S-Codes and H-Codes,* 22.0*).* Providers need to use alternate available CPT or HCPCS codes to report for the service. If no specific CPT or HCPCS code is available, then an unlisted code may be used. Note that unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. Thus, if an unlisted code is billed related to a non-covered service addressed in this policy, it will be denied as not covered.

CODES*		
CPT	None	
HCPCS	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
	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)
	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 month
	A9270	Non-covered item or service
	A9275	Home glucose disposable monitor, includes test strips
	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
	E2104	Home blood glucose monitor for use with integrated lancing/blood sample testing cartridge
	S8490	Insulin syringes (100 syringes, any size) *(CMS-assigned Status "I" code – See above billing guidelines)*

***Coding Notes:**

- The code list above 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. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does **not** make a procedure medically reasonable or necessary or a covered benefit by Medicare. *(Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)*
- 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. Medicare Physician Fee Schedule (PFS) Relative Value Files; Available at: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Relative-Value-Files

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
9/2022	Annual review (converted to new format 2/2023)
8/2023	Interim update; corrections to configuration of some codes
11/2023	Annual review; add replacement criteria
4/2024	Q2 2024 code updates