

December 21, 2023

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Re: Test Cartridge with Automated Blood Sampling HCPCS Level II Coding Consideration

Dear Mr. Bennett,

The Diabetes Dietetics Practice Group, a subunit of the Academy of Nutrition and Dietetics, represents more than 4,000 registered dietitian nutritionists that work with individuals who have diabetes. The value of glucose monitoring data in clinical diabetes management is critical for making nutrition and medication decisions¹.

Glucose monitoring serves as a pivotal tool for both health care providers and patients², and is used to easily facilitate glucose fluctuation data from the effects of dietary intake, physical activity, medication usage and stress. This monitoring method plays a vital role in averting hypoglycemic or hyperglycemic events, mitigating potential complications and empowering individuals to make informed choices, thereby ensuring optimal blood sugar levels and overall health³.

We urge your support of developing a new code and reimbursement that accurately describe cartridges needed for automatic blood glucose monitoring systems as detailed in the November 28, 2023 Biannual 2023 Healthcare Common Procedure Coding System Public Meeting. In present state, the E2101 code (*Blood glucose monitor with integrated lancing/blood sample*) assigned by the Pricing, Data Analysis and Coding, enables access to automatic glucose monitoring systems. However, to utilize an automatic blood glucose monitor, beneficiaries also need access to a specific test cartridge. Existing HCPCS codes for lancets and test strips do not appropriately describe the automatic test cartridge.

Numerous factors may render self-monitoring blood glucose more suitable for patient use compared to continuous blood glucose monitoring. Skin reactions or allergies^{4,5} to the adhesives

¹Peggy Soule Odegard, Jennifer Rose Beach; Blood Glucose Monitoring: A Practical Guide for Use in the Office and Clinic Setting. *Diabetes Spectr* 1 April 2008; 21 (2): 100–111. <https://doi.org/10.2337/diaspect.21.2.100>

²<https://www.adces.org/diabetes-education-dsmes/adces7-self-care-behaviors>

³American Diabetes Association Professional Practice Committee; 7. Diabetes Technology: Standards of Medical Care in Diabetes—2022. *Diabetes Care* 1 January 2022; 45 (Supplement_1): S97–S112. <https://doi.org/10.2337/dc22-S007>

⁴doi: 10.1089/dia.2019.0171. Epub 2019 Jul 25. PMID: 31335203.

⁵Rigo RS, Levin LE, Belsito DV, Garzon MC, Gandica R, Williams KM. Cutaneous Reactions to Continuous Glucose Monitoring and Continuous Subcutaneous Insulin Infusion Devices in Type 1 Diabetes Mellitus. *J Diabetes Sci Technol*. 2021 Jul;15(4):786-791. doi: 10.1177/1932296820918894. Epub 2020 May 9. PMID: 32389062; PMCID: PMC8258506.

utilized in CGM sensors can cause discomfort or infeasibility in continuous monitoring for certain individuals. Economic and technological proficiency limitations^{6,7} may hinder some individuals from adequately employing CGM devices and interpreting data, impacting their adoption and effective use. Furthermore, some CGMs require the user to verify their readings or trends with a BGM⁸ prior to making treatment decisions. It is imperative to highlight the challenges faced by individuals with limited manual dexterity⁹, such as those with arthritic hands, when using traditional blood glucose monitors; the multi-step process and manual dexterity required for accurate testing can pose significant difficulties for this population. Further, this group may also experience economic constraints underscoring the necessity of automatic blood glucose monitoring systems.

The functionality of automatic blood glucose monitoring systems and their associated test cartridges has simplified the testing process for patients, while mitigating several of the dexterity issues that arise with the use of traditional blood glucose monitors. Automatic blood glucose monitoring systems have the potential to reduce cost related to wasted test strips, which makes this option even more appealing to both the patient and provider.

Recently, an Academy member shared her experience about a beneficiary who was having challenges monitoring her blood glucose levels at home. The beneficiary recently stopped testing her blood sugar because it was too difficult to complete the test due to hand tremors while attempting to puncture her finger and transfer blood to the test strip. To address this challenge, the registered dietitian nutritionist provided the beneficiary with an automatic blood glucose monitoring system, which includes both the meter and cartridge. This intervention successfully allowed the beneficiary to test her blood sugar, mitigating the obstacles previously encountered.

The provision of an automatic blood glucose monitoring system proved instrumental in allowing the beneficiary to overcome physical limitations to ensure consistent blood sugar monitoring. Creating a code that allows for adequate coverage of test cartridges with automated blood sampling is essential to facilitate accessibility for individuals like the afore mentioned beneficiary, who are facing physical limitations and promote effective self-management of diabetes while improving overall health outcomes. This also aligns with inclusive healthcare practices and addresses specific needs, fostering a patient-centered approach to support those with unique challenges.

The Academy of Nutrition and Dietetics supports improving access to innovative technology that promotes and advances the health of Medicare beneficiaries. Additionally, we believe that improving access to such technology is a step towards achieving health equity. In 2021, the Centers for Medicare & Medicaid Services issued the *Disparities in Diabetes Care Among Medicare Fee-for-Service Beneficiaries*,¹⁰ which highlighted that diabetes disproportionately affects racial

⁶ Vransy EA, Hill-Briggs F, Ephraim PL, Myers AK, Garnica P, Fitzpatrick SL. Continuous glucose monitors and virtual care in high-risk, racial and ethnic minority populations: Toward promoting health equity. *Front Endocrinol (Lausanne)*. 2023 Jan 25;14:1083145. doi: 10.3389/fendo.2023.1083145. PMID: 36761197; PMCID: PMC9905720.

⁷ Toschi E, Munshi MN. Benefits and Challenges of Diabetes Technology Use in Older Adults. *Endocrinol Metab Clin North Am*. 2020 Mar;49(1):57-67. doi: 10.1016/j.ecl.2019.10.001. Epub 2019 Nov 18. PMID: 31980121; PMCID: PMC6983469.

⁸ <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=33822&ver=55&DocID=L33822>

⁹ Mary M. Austin; The Two Skill Sets of Self-Monitoring of Blood Glucose Education: The Operational and the Interpretive. *Diabetes Spectr* 1 May 2013; 26 (2): 83–90.

¹⁰ [tps://www.cms.gov/files/document/diabetes-disparities-data-highlight-2021.pdf](https://www.cms.gov/files/document/diabetes-disparities-data-highlight-2021.pdf)

and ethnic minority populations in both prevalence and health outcomes. The authors note that disparities also exist in the quality of diabetes care, stating that "compared to non-Hispanic White individuals with diabetes, non-Hispanic Black individuals in the general and Medicare populations have lower rates of meeting glycemic and blood pressure control targets." Technology such as blood glucose monitoring empowers individuals to fully engage in clinical recommendations and in turn make informed health decisions further bridging gaps in healthcare access, while fostering a more inclusive and equitable healthcare landscape.

The Academy commends CMS for the recent changes in the continuous glucose monitoring coverage policy and enhancing diabetes management accessibility for seniors. There remains an essential requirement for beneficiaries to have access to blood glucose meters and corresponding cartridges. We urge CMS to establish an avenue to make both automatic blood glucose monitors and their respective cartridges accessible within the Medicare program; specifically, the Academy requests the development of a HCPCS code that describes the uniqueness of an automatic blood glucose monitoring cartridge.

The Academy appreciates CMS' consideration of this request. Please contact Carly Leon, director of Healthcare Policy and Payment at cleon@eatright.org or via phone at 312-899-1773 with any questions or concerns.

Best Regards,



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