



January 4, 2021

Ms. Seema Verma, MPH
Administrator
Centers of Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1738-P
P.O. Box 8013
Baltimore, MD 21244-8010
Submitted via www.regulations.gov

Re: CMS-1738-P: Medicare Program; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Policy Issues and Level II of the Healthcare Common Procedure Coding System (HCPCS)

Dear Administrator Verma:

Beyond Type 1 is honored to have the opportunity to provide comments on the above-referenced proposed rule published November 4, 2020 in the Federal Register.

Beyond Type 1 is a nonprofit organization changing what it means to live with diabetes. Through platforms, programs, resources, and grants, Beyond Type 1 is uniting the global diabetes community and providing solutions to improve lives today. Founded in 2015 with a focus on education, advocacy and the path to a cure for Type 1 diabetes, Beyond Type 1 has grown to also include programs for those with Type 2 diabetes (Beyond Type 2). We speak as experts and leaders in the lived experience.

Patients Over Paperwork

We would like to thank you for introducing and embracing the Patients Over Paperwork Initiative at CMS. We are mindful that the intent of the proposed changes is to benefit not just CMS by decreasing inefficiencies and healthcare professionals by putting care ahead of administrative burdens, but also people with diabetes through removing barriers to innovation.

As part of this effort, we would like to applaud the DME MAC's proposed change to LCD of the elimination of the burdensome 4x/day BGM paperwork requirements for beneficiaries to obtain

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CGM is a significant step in helping people with diabetes access the devices they need for daily management. We look forward to seeing further barriers removed, including but not limited to an updated scientific review and subsequent removal of c-peptide testing as part of eligibility criteria for insulin pump therapy.

Our comments focus on Section VI of the proposed rule (beginning on p. 70398 of the Federal Register) regarding Continuous Glucose Monitors (CGM) and the rule's impact on access and safe management of diabetes in Medicare beneficiaries, both currently and in the future.

CMS Willingness to Expand Access to All CGM as DME

Beyond Type 1 believes that access to diabetes technology, including CGM, should be widespread, affordable, dependable, and most importantly, accurate for optimum daily diabetes management. While in commercial existence for home patient use for decades, the Centers of Medicare and Medicaid Services did not permit reimbursement until January 12, 2017, as non-adjunctive labeling (also termed as therapeutic in the proposed ruling) was a requirement.

The CMS ruling (CMS-1682-R) stated clearly that adjunctive (also termed as non-therapeutic) CGM would not be reimbursed. Current CGM products without a therapeutic designation but are FDA approved exist, requiring blood glucose confirmatory fingersticks before treatment. Individuals on Medicare using adjunctive CGM products since 2017 have filed for reimbursement in federal district courts, with multiple judges ruling that systems serve a medical purpose through alarms while a beneficiary is asleep and should be reimbursed.

We appreciate the willingness of CMS to explore an expansion of CGM reimbursement to include non-therapeutic products.

Patients and caregivers need to trust CGM to provide meaningful, actionable data for diabetes treatments. As we look into the future, additional technological complexity (the addition of stand-alone algorithms, apps, and systems that do not include pumps) will cement the need for accuracy and reliability of CGM.

CMS Should Reconsider Categorization of CGM

While not explicitly stated, three suggested categories with reimbursement changes are extrapolated from pages 70402-70404 of the Federal Register:

1. Automatic, adjunctive (Fingerstick glucose confirmation required before treatment.)
2. Automatic, non-adjunctive (Fingerstick glucose confirmation not required.)
3. Manual, non-adjunctive (Fingerstick glucose confirmation not required.)



Beyond Type 1 feels that this is the most significant change in the proposed ruling and one in which we, as the voice of the patient community, have serious concerns, as this segmentation will have an impact on device access long-term for beneficiaries.

We recognize that the creation of categories is directly tied to the addition of adjunctive CGM reimbursement. As therapeutic decisions cannot be made without a fingerstick for these CGM, beneficiaries must also have a BG monitoring system, which requires reimbursement for both CGM and BGM. The adjunctive category fee schedule removes the fee associated with BGM reimbursement (meter and strips) from the Automatic, Adjunctive category.

There however appears to be an arbitrary category split in the non-adjunctive category between “automatic” and “manual.” Before the proposed ruling, the current 2020 monthly fee schedule for all CGM supplies is (\$222.77 for Class II/\$259.20 for Class III); while the automatic classification remains at this reimbursement rate, the “manual” reimbursement rate is reduced to \$46.86 for Class II/\$52.01 for Class III). This appears to be an error, with this possibly being per sensor, rather than per month. If this ruling stands, this type of sensor will be hard to find for the over 100,000 beneficiaries currently using this type of CGM. This is the antithesis of the Patients Over Paperwork Initiative that CMS has adopted, forcing thousands of hours of unnecessary clinical hours, paperwork, and hardship for patients due to this avoidable disruption.

Therefore, we do not agree with the proposed categorization. While we believe that it is appropriate to back out the cost of BGM supplies if the CGM is non-therapeutic, we do not believe it is appropriate to increase the number of categories for this monthly fee schedule.

The creation of three categories within three years of the initial ruling is premature, as the expectation of new iterations of CGM within the next five years will then require additional rulings. This proposed ruling creates a slippery slope and is not warranted at this time.

Thank you for reviewing and considering the comments we have provided. If you have any questions or wish to discuss our thoughts in more detail, please contact me at caprigliano@beyondtype1.org or 404-863-2345.

Sincerely,

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