AFFIDAVIT OF NICHOLAS B. ARGENTO, MD

1. I, Nicholas Argento, M.D., make the following statement regarding my own personal knowledge and experience with the use of continuous glucose monitoring (CGM), and if called upon, could competently testify to the issues herein.

2. I graduated from Georgetown University magna cum laude, was elected to the Alpha Omega Alpha Honor Medical Society as a Junior, and received my M.D. degree cum laude from the University of Maryland in 1985.

3. I am board-certified in both Internal Medicine, and in the specialty of Diabetes, Endocrine and Metabolism, and was among the first clinicians to be certified as a Diabetes Technology Clinician.

4. I am licensed by the state of Maryland, where I practice in good standing, and have been in full time clinical practice in Endocrinology and Diabetes since 1991, and I currently serve as the Diabetes Technology Director of Maryland Endocrine, PA, a 10 physician Endocrine and Diabetes specialty practice.

5. I was co-author or contributor to multiple chapters in the 2013 American Diabetes Association book, *Putting Your Patients on the Pump, 2nd edition.*

6. I have made numerous presentations to local, regional, national, and international medical professional audiences on the application of CGM in clinical practice, and have published several peer-reviewed articles on CGM use in diabetes management, including an article that evaluated continuous glucose monitoring in patients over the age of 65. My C.V. is attached hereto.

7. Numerous studies on CGM have been published in peer-reviewed medical journals including multiple randomized clinical trials. These studies meet or exceed the quality of other studies exploring treatment options for Type 1 diabetes ("T1D").

8. Continuous glucose monitors are recognized as the standard of care for T1 D who have hypoglycemia unawareness or have suffered episodes of severe hypoglycemia. Numerous professional societies, including The Endocrine Society, the American Association of Clinical Endocrinology, and the American Diabetes Association, have issued guidelines that endorse the use of personal CGM for patients who suffer from hypoglycemia or hypoglycemia unawareness, which are recognized as highly dangerous conditions, or those who have maintained average blood glucose above recommended goal levels despite efforts to improve their degree of control.

9. Nearly all commercial payers in the United States and the Veteran's Administration Medical System cover continuous glucose monitors in view of the professional standards, clinical need, and cost-effectiveness. In fact, many of the Medicare Secondary plans, such as the Federal Blue Cross plan, continue to cover CGM for

Medicare beneficiaries after denial by CMS because it is considered necessary, highly clinically efficacious, and cost-effective.

10. I prescribe CGM for T1D patients who are:

    a. unable to adequately control their type 1 diabetes despite effort on their part to do frequent fingerstick blood glucose monitoring, take multiple insulin injections per day, and/or use an insulin pump; or
    b. have the extremely dangerous condition of hypoglycemia unawareness, a condition wherein the patient is unable to either recognize serious impairment from hypoglycemia or mount an effective physiologic defense against hypoglycemia; or
    c. suffer from episodes of severe hypoglycemia (meaning blood glucose levels below 50-55 mg/dL, regarded as an imminently life threatening degree of hypoglycemia), or who have required outside assistance to recognize and correct bouts of hypoglycemia.

11. I have personally prescribed CGM for hundreds of patients, dozens of whom are aged 65 or older, whom I continue to actively manage.

12. I have successfully assisted at least one Medicare beneficiary in securing coverage for CGM. I am aware that various administrative law judges have recognized that CGM is necessary for Medicare beneficiaries who are T1D and suffer from uncontrolled T1D.

13. I conducted a retrospective study of CGM that explicitly evaluated the outcomes of CGM technology in the population 65 years or older. The study showed significant and durable improved glycemic control when CGM was used, demonstrating a 68% reduction in the rate of dangerous severe hypoglycemia episodes, and noted that Medicare non-coverage was the primary factor for not following the recommendation to start or continue CGM use in this population.

14. A patient included in this study, one who was not using CGM due to lack of CMS coverage, appears to have died from severe nocturnal hypoglycemia. A second disabled Medicare beneficiary, who was not included in the study because he was not 65, but who had a compelling need for CGM based on numerous and repeated episodes of severe hypoglycemia and marked hypoglycemia unawareness despite all possible interventions, also did not have CGM because he could not afford to self pay, died after a fall off a roof that broke his neck under circumstances highly suspicious for another severe hypoglycemia episode. See Attachment hereto.

15. Severe hypoglycemia is considered to be particularly dangerous in older patients, and is associated with increases in the risks of falls with injury, myocardial infarcts, cardiac arrhythmias, temporary or permanent cognitive impairment, seizures, motor vehicle accidents, and death. I have seen all of these poor outcomes result from hypoglycemia episodes in Medicare age T1D patients.

16. The rate of severe hypoglycemia has been shown to be the higher in older type 1 patients compared to other age groups, even those under expert care. Further, a strategy to loosen glycemic goals in older patients, with the hope that this might reduce the rate of severe hypoglycemia, has been demonstrated to be ineffective: the medical literature shows that those with high average blood sugar levels still suffer a high rate of severe hypoglycemia episodes.

17. I was approached by a district attorney, who asked if he could charge a T1D with criminal neglect because he caused a horrific car accident that left a small child in a coma and the father crippled. Because the person had hypoglycemia unawareness, I explained that the DA was not likely to prevail in such a case. The T1D driver was NOT using CGM, use of which has been proven to reduce the incidence of severe hypoglycemia episodes and reverse or improve hypoglycemia unawareness, and thus might have prevented this tragic outcome.

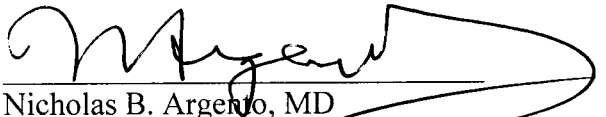
18. For those T1Ds who have hypoglycemia unawareness, GCM is no more precautionary than brakes are for a car. Without either, there is a serious and significant risk of physical harm, including death, and significant financial consequences. And like a car without brakes, a hypoglycemic driver is a public health menace, putting all of us at risk.

19. It is difficult to imagine anyone with adequate medical training who would deem CGM to be "precautionary" for T1Ds who have hypoglycemia unawareness or suffer from severe hypoglycemia episodes, any one of which can result in a tragic outcome.

20. Hypoglycemia unawareness often results from undetected nocturnal hypoglycemia, and even patients who monitor their blood sugars multiple times during the day, cannot monitor their blood sugars with fingersticks while they are asleep. CGM is a proven, medically necessary, readily available, effective therapy that allows successful management of such a patient's medical condition.

21. The need of such patients for CGM is compelling. The threat is dire. They are often long term survivors of what was once an almost uniformly deadly disease, T1D. Non-coverage of CGM is not medically justifiable, denies access to the standard of care afforded to nearly all younger patients, and therefore must be considered cruel.

I certify, under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed this 5th day of April, 2015.



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