HERC Coverage Guidance: Continuous Glucose Monitoring in Diabetes Mellitus
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Commenters

Identification	Stakeholder
A	Bruce Boston, MD; Kara Connelly, MD; Ines Guttmann Bauman, MD; Kelly Keller, PA; Lisa Madison, MD; Lindsey Nicol, MD; Melinda Pierce, MD; Joan Kono, RN CSN-PP CDE *[Submitted May 5, 2017]*
B	John Thomas Maluski *[Submitted May 21, 2017]*
C	Tracy Ann, RN *[Submitted May 24, 2017]*
D	Tomas C. Walker, DNP, APRN, CDE, on behalf of Dexcom, Inc. *[Submitted May 24, 2017]*
E	Duncan Williams, on behalf of Abbott Diabetes Care *[Submitted May 25, 2017]*

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A1	<u>Benefits of continuous glucose meters (CGMs) in childhood type 1 diabetes</u> Our main goal of treatment in children with type 1 diabetes, as in adults, is to normalize blood sugars as much as possible without dangerous hypoglycemia. A secondary goal is to allow the child and family to have minimal disruption to normal life, by reducing the burden of disease management, and to foster in the child the development of healthy coping skills for this lifelong chronic illness. Management of pediatric type 1 diabetes is more challenging than adult type 1 diabetes. Insulin requirements for pediatric patients change frequently due to growth and puberty	*Thank you for your comments. The commenter's statements regarding the evidence for CGM in children are consistent with the findings of the evidence review. The current coverage guidance provides for the use of CGM in children with type 1 diabetes.*

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	and frequent changes in activity levels. Children are less able to sense hypoglycemia, particularly in the toddler age group. Frequent capillary blood glucose (CBG) testing has for years formed the mainstay of modern diabetes management, used to monitor the effect of insulin dosing, protect against hypoglycemia, and calculate insulin doses. In recent years, CGM's, specifically CGM's that allow real time and remote monitoring of blood sugars (RT-CGM), are rapidly gaining traction as an important tool for diabetes management. <u>1. Glycemic control</u> Improved glycemic control, as judged by HbA1c, is used as a proxy for glycemic control and has clearly been shown to be associated with reduction in long term diabetes complications. As concluded by the HERC committee meta-analysis, CGMs have been shown to significantly lower HbA1c in adults. Significant lowering of HbA1c in children and young adults with type 1 diabetes using CGM has not clearly been demonstrated as yet, although most studies show trends towards improved HbA1c. It seems most likely that this difference is due to the difficulties in performing clinical studies in childhood: relatively low numbers of subjects and reduced adherence to CGMs in the pediatric patient age group. In addition, these studies were generally performed with older CGM devices: newer devices are more accurate and we are finding a much greater uptake and adherence to CGM technology in our pediatric age group in recent years. <u>2. Reduction in hypoglycemic events</u> CGM technology, with real time display of glucose values, offers great promise with respect to the detection and prevention of hypoglycemia. Children are at particularly high risk of hypoglycemia due to high insulin sensitivity, variable insulin needs, and variable activity levels. Furthermore, they have poor awareness of hypoglycemia, and in the youngest age	

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	ranges, they or their caregivers are often not able to detect any warning signs of hypoglycemia. This often leads families to prefer their child run higher blood sugars than optimal, particularly at night, negatively impacting HbA1c. Nevertheless, severe hypoglycemia is a rare event in modern diabetes management. Rates of severe hypoglycemia in children using RT-CGMs have been shown to be reduced in some studies, and unchanged, with improved HbA1c, in others. Importantly, studies have also shown a reduction in 'time in hypoglycemic range' in children wearing RT-CGMs. <u>3. Improved quality of life/psychosocial adaptation</u> Caring for a child with diabetes imposes a substantial burden on families. Parents of children diagnosed very young, in particular, may wake every night for years to check their child's blood sugar, out of fear of hypoglycemia. Burnout, particularly in teens and parents of teens, is high. CGM monitoring of blood sugars, particularly overnight, brings substantial peace of mind to families who are able to use the technology correctly. The ability to remotely monitor their child's blood sugar whilst they are at school is another tremendous benefit to families, and the use of CGM has been shown to reduce missed days at school. <u>4. Partial replacement for capillary blood glucose (CBG) testing</u> RT-CGM accuracy has improved to the point where one of the most popular CGM devices (Dexcom G5) has an error rate comparable to standard blood glucose meters. This has led the FDA to recently approve Dexcom readings to replace CBG testing for insulin dose calculation in children >2 years and adults. Thus, RT-CGM is likely to reduce the burden of painful, intrusive, and repetitive blood sugar testing that we currently require of our patients. Reduction in use of test strips may result in a cost benefit for insurance, in addition.	

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	Summary For these reasons, we believe that RT CGM technology should be an option available to all children with type 1 diabetes in Oregon. The main US professional endocrine societies (AACE, ADA, Endocrine society) all support the use of CGM in this age group. Children with type 1 diabetes are a particularly vulnerable group, and the ability to monitor blood sugars in real time offers substantial benefit, not least of which is peace of mind for the family. Patient selection is extremely important. Not all families are able to benefit from CGM: for some the additional data CGM systems provide can be overwhelming and confusing, despite education, and others find that the child cannot tolerate wearing the device. The decision regarding who may benefit from CGM is best individualized and left to an experienced pediatric diabetes provider. Education on how to use CGM effectively is also extremely important for successful outcomes, and should be provided by a trained pediatric diabetes educator. A trial of use may also be helpful. Overall, adherence is improving rapidly with improvements in sensor size and application, and CGM data may well reduce the frequency of CBG pokes, providing some cost offset. Very young children with type 1 diabetes are potentially a group who may benefit the most from RT-CGMs because of rapid blood sugar variation and lack of glycemic awareness. Unfortunately studies in this group are limited. The pace of improvement of the technology is rapid, with the development of partial 'closed loop' systems for those patients on pumps, allowing insulin delivery to be suspended when a rapid fall in blood sugar is detected, and/or adjustment of insulin basal rates based on blood sugar trend. This 'next generation' of integrated pumps and RT-CGM systems is likely to evolve rapidly over the coming few years.	

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B1	I am a retired Federal Government secondary school teacher having taught at Chemawa Indian School in Salem, Oregon and Osan American High School in Pyongtaek, Republic of Korea. I am merely providing an anecdotal narrative of my personal experience with Type 1 Diabetes and the use of an insulin pump with a continuous glucose monitor. I was diagnosed with Type 1 Diabetes in July, 2007 at the age of 62. I had never been tested as pre-diabetic in my life. My pancreas basically stopped and its function became virtually nil per a C-peptide test. Following my diagnosis of Type 1 Diabetes, I tested my blood glucose (BG) approximately 4 times daily. I injected Insulin Lispro (Humalog) and Insulin Lantus in order to control my diabetes. I had great difficulty in maintaining an HbA1C test in acceptable areas (in the 7's). I started using the Medtronic Paradigm Insulin Pump with a Continuous Glucose Monitor (CGM) in early 2008. My doctor informed me that I was extremely "brittle" and probably one of her most difficult cases in attaining BG control. I have used the Medtronic Insulin Pump with a CGM since that time until the present. My HbA1C tests are for the most part always in the mid to upper 6 range. I have never been to the emergency room or hospitalized for uncontrolled diabetes, even though my BG will range on a weekly basis, from the 300s to the 60s. For the most part I operate between 100 and 200 BG. If I miss dosing even for one meal I will easily reach a BG of 400. And, if I miscalculate a meal I can go into the 60's. Yet, I keep control of my diabetes because the CGM provides me an early warning in order to take action to treat my diabetes. I believe I would be very helpless without the CGM, being required to provide a finger stick test several times daily in order to keep the same type control I reach with my CGM. I currently test 3 to 4 times daily in order to recalibrate my CGM. I have met other	*Thank you for your comments. This coverage guidance recommends coverage, although it will not affect coverage for Medicare recipients. It may, however, influence coverage for the Oregon Health Plan and other payers.*

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	diabetics who use a pump but do not have a CGM. They are required to test as many as 7 to 8 times daily. Since my diabetes diagnosis I have suffered squamous cell throat cancer which had metastasized to my lymph system. I am fully recovered. I have had a heart attack and have had a stent emplaced, and I am recovered. I have had total knee replacement. And, I suffer from an auto-immune disease, dermatomyositis, for which I receive an infusion of Rituxin every 6 months. The surgery and treatment for these problems required that my diabetes was under control. Thanks to my CGM and proper HbA1C numbers, the doctors had no hesitation in performing their actions on me. Because I am on Medicare, age 72, I do not receive insurance coverage for the CGM, only the pump and infusion equipment. I purchase my own CGM's in order to live a lifestyle that allows me to exercise several days each week and to perform other activities that provide me pleasure. I fully endorse the use of the CGM.	

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C1	How is the 50% compliance determined and in what time period? 3-6-12 month follow-up? Some long term diabetics only see endocrinology once a year. Are the provider's determining compliance with a download? I have never seen CGM download on authorization requests. (I do DME authorization review for CareOregon.) These are expensive items to only have for 3 months as vendors do not rent them, but expect full payment. Is this DM equipment held to the 5 year DME rule? Currently DME providers are billing for 2 receivers and 1 transmitter every 12 months. Will there be additions to fee schedule?	*Thank you for your comments. Adherence can be determined using data from the CGM device. Providers can download data from CGM receivers that includes usage data and glucose levels. The subcommittee believed that adherence should be assessed by a clinician at an appropriate and patient-centered follow-up interval after the initiation of CGM.* *Implementation issues that are determined by individual health plans are not included in this coverage guidance, such as CGM device purchase versus rental agreements, authorization frequency for CGM supplies, and fee schedules.*
D1	On behalf of Dexcom, Inc., I'm writing to express my appreciation for the diligence applied to developing coverage guidance for continuous glucose monitoring (CGM) and the opportunity to provide comment. We concur with many of the recommendations; however, certain portions of the assessment reflect outdated information. With this letter, I'd like to address the use of obsolete CGM technology in systematic reviews and meta-analyses (SRMAs) and the "no-coverage" recommendation for adults with type 2 diabetes (T2D) and provide new information regarding Medicare coverage for CGM.	*Thank you for your comments.*
D2	<u>Obsolete Technology in Meta-Analyses</u> The Commission's review was heavily dependent upon SRMAs that include obsolete and discontinued CGM systems with relatively poor accuracy, as measured by the mean absolute relative difference (MARD) between CGM and contemporaneous blood glucose values. Several referenced sources, including the 2012 Cochrane Review,[1] base their conclusions on systems with MARD values in the 16-26% range, which is significantly worse than the 9% MARD of the Dexcom G5 Mobile System that was approved in 2015. In	*Thank you for your comments. The evidence review acknowledges that the accuracy of CGM devices has improved over time.* *The results from the type 2 diabetes cohort of the DIAMOND study remain unpublished (citation 5 is an oral abstract). Based on the oral abstract, the between-group difference in A1c after 24 weeks was -0.3% (95%*

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	general, findings from SRMAs for medical devices can be limited as technological advancements preclude differentiation of past and current devices.[2] Findings from older SRMAs may significantly underestimate the potential benefits of the latest devices. We appreciate the Commission's inclusion of the recently published DIAMOND[3] and GOLD[4] randomized controlled trials. The DIAMOND trial examined the impact of the CGM use in adults with T1D using multiple daily injections (MDI) with A1c values from 7.5% to 9.9%. Subjects randomized to CGM had excellent compliance (93% used it 6 or 7 days/week), and experienced a mean A1c decrease of 1 percentage point from baseline to week 24, compared to a 0.4 percentage point reduction in the control group (P <.001). Benefits were observed across all subsets including those subjects with lower education, poorer numeracy skills, and higher baseline A1c levels. These data are complemented by those from the GOLD study that was conducted in Sweden. Again, use of CGM was shown to result in lower A1c values and reduced hypoglycemia in people with T1D using MDI. The DIAMOND study also included a cohort of 158 patients with T2D who were using MDI. As with subjects with T1D, subjects with T2D used CGM 6.7±0.9 days/week, were highly satisfied with the technology, and significantly reduced their A1c values.[5] In summary, clinical outcomes from studies such as DIAMOND and GOLD that use up-to-date CGM systems show clinically meaningful and statistically significant benefits for patients with either T1D or T2D. These favorable results are likely to extend to larger populations with access to tools and technologies in the rapidly-evolving category of therapeutic CGM.	*CI -0.5% to 0.0%) in favor of CGM over the control arm. This finding is similar to the meta-analytic estimate of A1c improvement for patients with type 2 diabetes cited in the coverage guidance.*

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D3	<u>Real-time CGM is not recommended for coverage in adults with T2D</u> The Commission's recommendation of non-coverage for adults with T2D poses risks for patients on intensive insulin therapy (IIT). Large RCTs have shown that IIT increases the risk of severe hypoglycemia by 2- to 3-fold in patients with T1 and T2D.[6-8] Incorporating CGMs into the management of insulin-treated T2 patients would reduce hypoglycemia and result in safer and potentially better overall control, as hypoglycemia remains an important risk of therapy intensification.[9] Considerable data have emerged on the incidence, risk, and costs arising from hypoglycemia among patients with T1D or insulin-treated T2D.[5,10-13] Based on the accumulated evidence, professional societies have published guidelines recommending CGM for patients with either T1D or T2D who are at risk for hypoglycemia, as follows: • ADA Standards of Care 2017[14] o CGM is recommended in patients with T1D and those with hypoglycemia unawareness or frequent hypoglycemia. • AACE and ACE Outpatient Glucose Monitoring Consensus Statement[15] o CGM usage has improved diabetes outcomes by reducing hypoglycemia and should be used in all patients who have severe hypoglycemia. • Endocrine Society Clinical Practice Guideline 2016[16] o We recommend RT-CGM devices for adult patients with T1DM who have A1c levels above target or well-controlled T1D. • AACE and ACE CGM Consensus Conference 2016[17] o Participants unanimously agreed that RT-CGM should be available to all insulin-using patients regardless of diabetes type.	*IIT may increase the risk of hypoglycemia, but data on CGM from RCTs and systematic reviews of RCTs have not demonstrated a reduction in the incidence of severe hypoglycemia.* *The professional society statements are noted. The AACE and ACE CGM Consensus Conference acknowledge that their conclusion is "based entirely on studies conducted in T1D." They also acknowledge uncertainty about the benefits for patients with hypoglycemia unawareness: "Few studies have been conducted in patients with hypoglycemia unawareness due to challenges recruiting a suitable patient population, but it is likely that this population would also benefit from CGM…"*

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D4	<u>Medicare</u> On January 12, 2017, CMS announced the benefit category of non-adjunctive CGMs.[18] The ruling classified CGMs into "therapeutic" and "non-therapeutic" systems, with the former defined as those that can be used to replace fingerstick blood glucose testing for diabetes treatment decisions. Such systems are classified as durable medical equipment (DME) within the scope of Medicare Part B. Currently, *Dexcom G5 Mobile is the only device which meets the therapeutic CGM device classification.* On May 18, 2017, a Glucose Monitors Local Coverage Determination (LCD) and Related Policy Article was revised[19] to reflect the CMS ruling. Per the LCD, therapeutic CGMs may be covered by Medicare when all of the following are met: • The beneficiary has diabetes and, • Has been using a BGM and performing frequent (four or more times a day) testing; and, • Is insulin-treated with MDI or a Medicare-covered CSII pump; and, • The insulin regimen requires frequent adjustment on the basis of BGM or CGM testing results; and, • Within six months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria are met; and, • Every six months following the initial prescription of CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM and treatment plan.	*The subcommittee is aware of the CMS designation of the Dexcom G5 Mobile device as therapeutic CGM and the related LCD. We have updated the coverage guidance to include the new LCD.*

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D5	Based on the above, we respectfully request that the Health Evidence Review Commission: 1) Place greater emphasis on clinical outcomes associated with recently published RCTs which use currently available devices. 2) Update the assessment to reflect CMS Ruling 1682R, revised LCD for glucose monitors and coverage criteria for therapeutic CGM. 3) Align with Medicare and recommend therapeutic CGM for people with either T1D or T2D who are on ITT.	*See responses to D2, D3, and D4 above.*
E1	On behalf of Abbott Diabetes Care, I am pleased to submit comments in response to the above-referenced draft coverage guidance. In the draft guidance, the Commission recommends (weak recommendation) coverage of real-time continuous glucose monitoring ("CGM") in adults with Type I Diabetes Mellitus ("T1DM"): • Who receive diabetes education specific to the use of CGM and who have used the device for at least 50% of the time at their first follow-up visit; and, • Who have baseline HbAlc levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia. We strongly support this recommendation. By contrast, the Commission recommends against coverage for real-time CGM for adults with Type 2 Diabetes Mellitus ("T2DM") and for professional CGM for patients with T1DM and T2DM. We respectfully disagree with these latter recommendations as explained below. 1. Real-Time CGM Should be Covered for T2DM with Multiple Daily Insulin Injections ("MDI")	*Thank you for your comments.* *As noted above, the results from the type 2 cohort of the DIAMOND study remain unpublished (citation 1 is an oral abstract). Based on the oral abstract, the between-group difference in A1c after 24 weeks was -0.3% (95% CI -0.5% to 0.0%) in favor of CGM over the control arm. This finding is similar to the meta-analytic estimate of A1c improvement for patients with type 2 diabetes cited in the coverage guidance.* *The initial six-month results of the REPLACE study (citation 2) were published after the coverage guidance was drafted. The trial was designed as an open-label unmasked RCT with 2:1 randomization (n=224). Patients with less than 50% adherence during a blinded run-in period were excluded before randomization. There was higher loss to follow-up in the control group (17%) compared to the CGM group (6%). Comparisons of sensor-derived glycemic measures between the two*

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	There is new evidence, published after the HERC report, supporting the use of real-time CGM in adult patients with T2DM. a. DIAMOND Study The DIAMOND study was a 24-week randomized controlled trial conducted at 25 clinics across the United States and Canada that evaluated CGM versus a control group in T2DM with MDL 158 patients were randomly assigned to CGM or standard care. The mean HbA1c decreased from 8.5+0.6% (baseline) to 7.7+0.7% at 24 weeks with CGM versus 8.5+0.7% to 8.0+0.9% in the control group (adjusted difference= - 0.3%, 95% confidence interval -0.5% to -0.0%, p=0.02). The CGM group reported a high degree of satisfaction. Overall, a high percentage of adults with T2DM requiring MDI used CGM on a daily/near-daily basis for 24 weeks with a significant reduction in HbA1c and increased time-in-range ("TIR") compared with the control group.[1] b. REPLACE[2] The REPLACE study was a randomized, controlled study in adults with T2DM on intensive insulin therapy from 26 diabetes centers. 224 participants were randomly assigned (2:1) to the Abbott FreeStyle Libre™ Flash Glucose Monitoring System for self-management or to the self-monitoring of blood glucose ("SMBG") control group. Participants in the intervention group who successfully completed the 6-month trial continued into a 6- month open-access phase. At the end of the 1 2-month period, "time in hypoglycemia [sensor glucose <3.9 mmol/L (70 mg/dL)] was reduced by 50% compared to baseline [-0.70 ± 1.85/24 h (mean ± standard deviation)" and nocturnal hypoglycemia was reduced by 52%p=0.0002 (for both results) in favor of the intervention group. Overall, the use of flash glucose-sensing technology was "associated with a sustained reduction in hypoglycemia and safely and effectively replaced SMBG."[3]	*groups represent only the final two weeks of the study period (days 194–208), during which the control group participants wore a blinded sensor. There was no correction for multiple testing of secondary endpoints including the sensor-derived glycemic measures. Abbott Diabetes Care sponsored and funded the trial and was also involved in data collection and results reporting. All but one of the authors disclosed receiving personal fees from Abbott Diabetes care, and an employee of Abbot Diabetes Care provided "statistical support." There was no difference in the primary endpoint of change in A1c between the CGM and control groups at the end of six months. Secondary endpoints of time in hypoglycemia, nocturnal hypoglycemia, and frequency of hypoglycemic events (at various thresholds) were all reduced in the CGM arm, but severe hypoglycemia was not reported. (Patients with a history of severe hypoglycemia were excluded from the trial). CGM was associated with improved total treatment satisfaction as measured by the DTSQ (13.1 vs. 9.0 on a -18 to 18 point scale, with higher scores reflecting greater satisfaction), but there were no statistically significant differences in the perceived hypoglycemia or perceived hyperglycemia components of the DTSQ.* *Citation 3 is a six month open-access extension of the REPLACE trial and the outcomes were mainly sensor-derived glycemic measures compared to baseline values.*

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	These two studies published within the last three months provide substantial evidence to support coverage for real-time CGM for adults with T2DM with MDI. c. Medicare Coverage In January 2017, after HERC drafted its guidance, CMS published an administrative ruling that "therapeutic continuous glucose monitors (CGM) are covered under the Durable Medical Equipment benefit."[4] A coverage article and corresponding LCD outline the criteria for coverage under Medicare.[5,6] II. Professional (Retrospective) CGM Should be Covered for T1DM or T2DM with MDI Vigersky, et al. conducted a review of the role of CGM for patients with T2DM.[7] He noted "[p]rofessional and real-time CGM has been used primarily in patients with T1D and most of the evidence for its benefit is in that group...However, there has been growing evidence that those with T2D may benefit from the use of this technology by COM's ability to uncover previously unknown hypoglycemia...." This review presented results from 7 studies, including 5 RCTs, which showed 3-7 days of professional CGM result in improvement in HbA1C (0.6%-2.3%) in patients with T2DM. Medicare and many private payers cover professional (retrospective) CGM in patients with T1DM.[8] Some payers also provide coverage for professional CGM in T2DM with MDI especially to document hypoglycemia.[9] The systematic review and the coverage policies in support of professional CGM support coverage for professional CGM for T1DM and T2DM with MDI. We appreciate the opportunity to submit comments on this draft coverage guidance.	*As noted above, the subcommittee is aware of the CMS designation of the Dexcom G5 Mobile device as therapeutic CGM and the related LCD.* *The manuscript by Vigersky and Srivastava (citation 7) is not a systematic review and no methods are described. The relevant evidence table included in the review is entitled "Studies demonstrating improved HbA1c." This leads to the question of whether additional studies exist that do not demonstrate improved HbA1C.*

References Provided by Commenters

ID/#	References
D	1. Langendam M, Luijf YM, Hooft L, Devries JH, Mudde AH, Scholten RJ. Continuous glucose monitoring systems for type 1 diabetes mellitus. Cochrane Database Syst Rev. 2012;1:CD008101. 2. Price D, Graham C, Parkin CG, Peyser TA. Are Systematic Reviews and Meta-Analyses Appropriate Tools for Assessing Evolving Medical Device Technologies? J Diabetes Sci Technol. 2015;10(2):439-446. 3. Beck RW, Riddlesworth T, Ruedy K, et al. Effect of Continuous Glucose Monitoring on Glycemic Control in Adults With Type 1 Diabetes Using Insulin Injections: The DIAMOND Randomized Clinical Trial. JAMA. 2017;317(4):371-378. 4. Lind M, Polonsky W, Hirsch IB, et al. Continuous Glucose Monitoring vs Conventional Therapy for Glycemic Control in Adults With Type 1 Diabetes Treated With Multiple Daily Insulin Injections: The GOLD Randomized Clinical Trial. JAMA. 2017;317(4):379-387. 5. Bergenstal R, Riddlesworth T, Ruedy K, Kollman C, Price D, Beck R. Patients with Type 2 Diabetes Using Multiple Daily Insulin Injections Have High Adherence and Benefit From CGM: A Prospective, Randomized Controlled Trial. Diabetes Technol Ther. 2017;19(S1):A11. 6. The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Engl J Med. 1993;329(14):977-986. 7. UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet. 1998;352(9131):837-853. 8. Action to Control Cardiovascular Risk in Diabetes Study Group. Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008;358(24):2545-2559. 9. Cryer PE. The barrier of hypoglycemia in diabetes. Diabetes. 2008;57(12):3169-3176. 10. Foos V, Varol N, Curtis BH, et al. Economic impact of severe and non-severe hypoglycemia in patients with Type 1 and Type 2 diabetes in the United States. J Med Econ. 2015;18(6):420-432. 11. Cariou B, Fontaine P, Eschwege E, et al. Frequency and predictors of confirmed hypoglycaemia in type 1 and insulin-treated type 2 diabetes mellitus patients in a real-life setting: results from the DIALOG study. Diabetes Metab. 2015;41(2):116-125. 12. Geller AI, Shehab N, Lovegrove MC, et al. National estimates of insulin-related hypoglycemia and errors leading to emergency department visits and hospitalizations. JAMA Intern Med. 2014;174(5):678-686. 13. Schopman JE, Geddes J, Frier BM. Prevalence of impaired awareness of hypoglycaemia and frequency of hypoglycaemia in insulin-treated type 2 diabetes. Diabetes Res Clin Pract. 2010;87(1):64-68. 14. American Diabetes A. 6. Glycemic Targets. Diabetes Care. 2017;40(Suppl 1):S48-S56. 15. Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. Endocr Pract. 2016;22(2):231-261. 16. Peters AL, Ahmann AJ, Battelino T, et al. Diabetes Technology-Continuous Subcutaneous Insulin Infusion Therapy and Continuous Glucose Monitoring in Adults: An Endocrine Society Clinical Practice Guideline. J Clin Endocrinol Metab. 2016;101(11):3922-3937.

ID/#	References
	17. Fonseca VA, Grunberger G, Anhalt H, et al. Continuous Glucose Monitoring: A Consensus Conference of the American Association of Clinical Endocrinologists and American College of Endocrinology. Endocr Pract. 2016;22(8):1008-1021. 18. Centers for Medicare and Medicaid Services. Ruling No.: [CMS-1682-R]. 2017. Available at: https://www.cgsmedicare.com/jb/pubs/news/2017/03/cope2581.html. Accessed May 24, 2017. 19. CGS Administrators L. Glucose Monitors LCD and Revised Policy Article. 2017; https://www.cgsmedicare.com/jb/pubs/news/2017/05/cope3241.html. Accessed May 18, 2017.
E	1. Bergenstal R, Riddlesworth T, Ruedy K, Kollman C, PriceD, Beck RW. Patients with type 2 diabetes using multiple daily insulin injections have high adherence and benefit from CGM: a prospective, randomized controlled trial. Paper presented at: 1Oth International Conference on Advanced Technology and Therapeutics (ATID); February 15-18, 2017; Paris, France. 2. REPLACE is the randomized controlled trial, "Novel Glucose-sensing Technology as a Replacement for Blood Glucose Monitoring for the Management of Insulin-treated Type 2 Diabetes" Page 1 DM_HC I080089-3 023560.0691 3. Haak T, Hanaire H , Ajjan R, Hermanns N, Riveline J, Rayman G. Use of Flash Glucose-Sensing Technology for 12 months as a Replacement for Blood Glucose Monitoring in Insulin-treated Type 2 Diabetes. Diabetes Ther. 2017 Apr II. doi: I0.1 007/s 13300-017-0255-6. 4. The ruling (CMS-1862-R) articulates CMS policy concerning the classification of continuous glucose monitoring systems as durable medical equipment under Part B of the Medicare program. 5. Glucose Monitor - Policy Article CA52464). 6. Local Coverage Determination by CGS Administrators and Noridian Healthcare Solutions, Glucose Monitors (L33822). 7. Vigersky R, and Shrivasta v M . Role of continuous glucose monitoring for type 2 in diabetes management and research. Journal of Diabetes and its Complications. 31.1 (2017): 280-287. 8. "Continuous Glucose Monitoring and Insulin Delivery for Managing Diabetes", UnitedHealthcare Commercial Medical Policy, April I, 20 1 7. "Continuous or Intermittent Monitoring of Glucose in Interstitial Fluid", Medical policy adopted by a number of Blues plans including Blue Shield of California, HCSC (BlueCross BlueShield of IL, TX, OK, N M, and MT), Blue Cross of Idaho, BlueCross BlueShield of Alabama, and others. "Continuous Interstitial Glucose Monitoring", Anthem Medical Policy, 2017. ''Home Blood Glucose Monitors", Cigna Medical Coverage Policy, 2017. 9. See the above policies from United, HCSC, and CIGNA among others.