

HERC Coverage Guidance – Continuous Glucose Monitoring in Type One Diabetes Mellitus Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
Medtronic Diabetes Northridge, CA	1	On behalf of Medtronic Diabetes, I am pleased to submit this response to the Oregon Health Evidence Review Commission and Health Technology Assessment Subcommittee with respect to the Draft Coverage Guidance on Continuous Glucose Monitoring. Medtronic appreciates the work Oregon HERC and HTAS has put forth this far to draft Coverage guidance for Continuous Glucose Monitoring.	Thank you for taking the time to comment.
	2	Based on the compelling and continually expanding data and trial results supporting the clinical value of CGM for patients with diabetes, we are in support of the draft guidance recommended at the June 25th meeting for Personal/Real-Time CGM. The guidance states that Personal/Real-Time CGM “should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c >8 for whom insulin pump management is being considered, initiated, or utilized.	Thank you for your comment.
	3	Medtronic however, does not agree with the recommendation on Retrospective (Professional) CGM. We do suggest that this device should be covered. Retrospective CGM provides Health Care Providers significant and meaningful insight to glucose patterns that otherwise would not be available. Health Care Providers utilize the data to help guide therapy, modify treatment regimens, and teach patients how food, activity, and personal involvement impacts their ability to better manage their disease. In addition, by not continuing to cover professional services (95250 and 95251) it would create disparity of care for the patients served in Oregon. All other payer entities in the state of Oregon including Medicare and all private/commercial payers including United Healthcare, Aetna, Cigna, Humana, Health Net, and Wellpoint/Anthem have coverage and payment for Retrospective CGM. We strongly urge HERC to continue to maintain coverage on line 10 of the Prioritized List of Services for Type 1 diabetes, and recommend that it be included for any insulin treated diabetes patient	The evidence source did not find a statistically significant difference in HbA1c levels or hypoglycemia in any trial that compared a retrospective CGM to control. The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers’ coverage policies.
	4	<u>Professional (Retrospective) CGM</u> 95250 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; sensor placement, hook-up, calibration of monitor, patient training, removal of sensor, and printout of recording 95251 Ambulatory continuous glucose monitoring of interstitial tissue fluid via a subcutaneous sensor for a minimum of 72 hours; interpretation and report	HTAS is aware of these CPT codes.
	5	Studies have shown that retrospective CGM detects glycemc excursions that were missed with SMBG and is particularly well suited to detecting asymptomatic hypoglycemia. CGM detected a longer duration of hypoglycemia than SMBG ¹ and identified episodes of postprandial hyperglycemia ^{2,3,4} nocturnal hypoglycemia ^{5,6,7} , ⁸ and asymptomatic hypoglycemia ^{9,10} that were frequently not identified by SMBG. In a study of elderly individuals with well-controlled Type 2 diabetes, CGM captured 103 episodes of hypoglycemia in 20 patients over four 72-hour periods of monitoring and detected elevated postprandial glucose levels after 57% of meals. ¹¹ None of the hypoglycemic episodes detected by CGM, many of which occurred at night, were recorded in patients’ diaries. CGM is the best tool for detecting episodes of asymptomatic and nocturnal hypoglycemia, both of which	The citations listed were published before the date of the Cochrane review (last search date June 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or

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		tend to occur more frequently in patients who have hypoglycemia unawareness. ¹²	excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	6	<p>Studies document the following benefits of CGM:</p> <ul style="list-style-type: none"> CGM detects glycemic excursions missed with SMBG. Studies have shown that CGM detects glycemic excursions that were missed with SMBG and is particularly well suited to detecting asymptomatic hypoglycemia. CGM detected a longer duration of hypoglycemia than SMBG,¹³ and identified episodes of postprandial hyperglycemia,^{14, 15, 16} nocturnal hypoglycemia,^{17, 18, 19, 20} and asymptomatic hypoglycemia^{21, 22} that were frequently not identified by SMBG. CGM is the best tool for detecting episodes of asymptomatic and nocturnal hypoglycemia, both of which tend to occur more frequently in patients who have hypoglycemia unawareness.²³ 	Assuming commenter is referring to retrospective CGM, see comment #5
	7	<ul style="list-style-type: none"> CGM improves diabetes management. The identification of glycemic excursion patterns can be used to reduce the incidence of hyperglycemia and hypoglycemia by making changes to patients' diabetes management plans, including 1) altering the insulin-to-carbohydrate ratio, 2) altering the basal insulin regimen, 3) using glucose tablets instead of food or juice to treat hypoglycemia, 4) reducing the amount of supplemental insulin needed to correct elevated blood glucose values, and 5) changing patients' approaches to exercise.^{24, 25} 	Assuming commenter is referring to retrospective CGM, see comment #5
	8	<ul style="list-style-type: none"> CGM improves diabetes outcomes. A substantial body of research has demonstrated that use of CGM by both adults and children can decrease A1C.^{26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36} 	Assuming commenter is referring to retrospective CGM, see comment #5
	9	<p>Evidence of CGM benefits is further reflected in professional standards. The AACE Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus include the following recommendation on use of CGM in type 1 diabetes:</p> <ul style="list-style-type: none"> Arrange for continuous glucose monitoring for patients with T1DM with unstable glucose control and for 	HTAS does not disagree with the use of CGM. The guideline referenced by the commenter does not specify that CGM should be retrospective.

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		patients unable to achieve an acceptable HbA1C level; continuous glucose monitoring is particularly valuable in detecting both unrecognized nocturnal hypoglycemia and postprandial hyperglycemia. ³⁷	
	10	The ADA's Standards of Medical Care in Diabetes - 2012 make the following CGM recommendations (Levels "A", "C", and "E", respectively) ³⁸ : <ul style="list-style-type: none"> • Continuous glucose monitoring (CGM) in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults (age > 25 years) with type 1 diabetes. (A) • Although the evidence for A1C lowering is less strong in children, teens, and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. • CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. 	See comment #9
	11	We hope that Oregon Health Authority finds this information useful in evaluating the benefits of continuous glucose monitoring technology. Should you have any questions regarding this information, please contact me.	Thank you for your comment.
<i>Physician, Associate Professor Portland, OR</i>	12	The purpose of this letter is to provide my opinion on the Draft Coverage Guidance on Continuous Glucose Monitoring by the Oregon Health Evidence Review Commission and Health Technology Assessment Subcommittee. Based on several clinical trials regarding the use of CGM in patients with diabetes, I am in full support of the draft guidance recommended at the June 25th meeting for Personal/Real-Time CGM. The guidance states that Personal/Real-Time CGM "should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c >8 for whom insulin pump management is being considered, initiated, or utilized.	Thank you for taking the time to comment.
	13	I am a specialist in diabetes and I see patients at the [clinic name removed] diabetes clinic. I believe that such a policy will help to minimize hypoglycemia and hyperglycemia in persons with type 1 diabetes, will minimize acute and chronic complications, and will thus improve their short-term and long-term quality of life.	Thank you for your comment.
<i>JDRF Washington, DC</i>	14	JDRF applauds the efforts of Health Technology Assessment Subcommittee (HTAS) in developing the draft guidance on CGM for Type 1 Diabetes. As JDRF's previous letter of June 21, 2012 to the HTAS indicates, we support broad coverage of CGM for those with type 1 diabetes (T1D), based on the extensive evidence of clinical benefit, the recommendations of all leading diabetes clinical care guidelines, and data on cost effectiveness. The Subcommittee's proposed draft guidance states that Personal/Real-Time CGM should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c >8 for whom insulin pump management is being considered, initiated, or utilized'. We believe this language is consistent with the clinical trial data from the 2006 JDRF funded trial and the series of published papers detailing the findings of the trial since 2008 highlighting the clinical effectiveness of CGM.	Thank you for taking the time to comment.
	15	JDRF however, has concern with the recommendation that retrospective (professional) CGM devices should not be covered and respectfully suggests that this language be reconsidered. We believe that retrospective CGM provides clinicians with critical insight to glucose excursions that otherwise would not be available. Patients'	The evidence source did not find a statistically significant difference in HgA1c levels or hypoglycemia in any

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		doctors utilize the data to help guide therapy, modify treatment regimens, and teach patients how food, activity, and personal involvement impacts their ability to better manage their disease.	trial that compared a retrospective CGM to control.
	16	In addition, eliminating coverage would create disparity of care for the patients served in Oregon. All other payer entities in the state of Oregon including Medicare and all private/commercial payers including United Healthcare, Aetna, Cigna, Humana, Health Net, and WellPoint/Anthem have coverage and payment for Retrospective CGM. Thank you again for consideration of our comments.	The HTAS makes its decisions based on evidence of effectiveness and harms, not on the basis of other payers' coverage policies.
Physician, Director of a diabetes health center Portland, OR	17	Thank you for your efforts in developing the guidance document on continuous glucose monitoring. I also greatly appreciated the opportunity to address the group at your meeting in June. I agree with your recommendations concerning the real-time continuous glucose monitoring systems. This is an important tool in the care of patients with type 1 diabetes that would be used sparingly and selectively to the benefit of appropriate subjects.	Thank you for taking the time to comment.
	18	During the June meeting I did not have time to comment on retrospective CGM. The guidance document refers to the lack of evidence for benefit and recommends against coverage for this tool. Although it is true that RCTs have not clearly shown benefit of retrospective CGM with regard to A1c reduction, for those of us who have used it, experience says it is a very important tool for some patients. I believe the manufacturers have not promoted extensive research in this area because the focus has been on real-time CGM. Nevertheless, most payers including Medicare have readily recognized the value of this technology. The cost is relatively low. There is plentiful evidence that CGM will identify unrecognized glucose fluctuations and hypoglycemia. The concept and intent are different than when using real-time CGM. Real-time CGM helps patients make moment-to-moment decisions on glucose values and trends as well as offering education when used to review the tracings. The emphasis with retrospective CGM is on identification of patterns that can be used by the provider to educate patients and to make safe adjustments in insulin. Most importantly, it identifies unrecognized hypoglycemia that is potentially life threatening. This is particularly important considering the fact that hypoglycemia is thought to be one of the leading causes of death in young individuals with type 1 diabetes. I have personally experienced at least a half-dozen patient deaths due to hypoglycemia and many others who have had severe injuries and other major consequences.	HTAS appreciates the concern about hypoglycemia, however, the evidence source did not find a significant difference in episodes of hypoglycemia in any trial that compared a retrospective CGM to control.
	19	Sometimes a single picture is worth a thousand words so I am including the following images from a retrospective CGM tracing done several days prior to the June meeting on a 30 year old teacher who was not aware of more than rare nocturnal hypoglycemia: [Graph located on next page]	While anecdotal experience has a strong influence on individual opinion, it is inherently susceptible to bias. High quality RCTs are the best way to assess true treatment effects, and the evidence examined by HTAS does not support the efficacy of retrospective CGM.

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	20	<p>Tue Jun 12 (mg/dL) Sensor</p> <p>Wed Jun 13 (mg/dL) Sensor</p>	See comment #19
	21	<p>This type of tracing is paired with a diary to indicate food intake, activity, insulin doses and other relevant events. As you can see, this patient had highly significant nocturnal hypoglycemia (< 50 mg/dl) on 3 of the 7 days tested by a retrospective sensor. She had no symptoms on any of these nights. It was frightening to find that she remained at dangerous levels of hypoglycemia for many hours during the night. This was definitely life-threatening and led to significant reductions in her insulin pump basal rates at night despite the fact that they were already much lower than daytime rates. I would like to think we avoided what would otherwise have been an eventual seizure or even a potential fracture falling out of bed or worst case, an arrhythmia.</p>	See comment #19
	22	<p>This is just one of many cases where findings on a retrospective CGM study resulted in important changes in therapy to improve safety or glucose control. In fact, I would estimate that >95% of such studies guide the provider to change insulin or behaviors to the benefit of the patient.</p>	Thank you for providing your clinical opinion.
	23	<p>Trying to help relate retrospective CGM to other common, covered procedures, I would have you consider ECGs, PFTs or possibly sleep studies. My guess is that ECGs in asymptomatic patients have never been shown to reduce the frequency of cardiac events by today's standards of evidence. Likewise, while PFTs can identify problems and guide therapy, they have likely never been subjected to RCT to show they directly improve outcomes.</p>	HTAS has not reviewed the evidence on ECGs or PFTs, but would require the same rigorous evaluation if they did.

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	24	I would be happy to provide literature to highlight studies showing identification of unrecognized long exposure to hypoglycemia if requested by the committee. The fact that most attention and studies have focused on real-time CGM speaks more to the business plans of device companies than to the potential advantage for patient care. Although you may want to restrict the use to specific situations and only with a limited frequency, I believe this is a tool that will not be costly and will serve patients and experienced type 1 diabetes providers well. Please consider a change in your recommendations.	Thank you for your comment. HTAS appreciates that impact of business on driving the research agenda, but notes that the evidence is not entirely lacking for retrospective CGM, with 7 studies in the evidence source.
Citizen/Patient Portland, OR	25	I am writing in response to the proposed coverage guidance for continuous glucose monitoring (CGM) use by people with Type 1 diabetes. I applaud your proposed coverage of CGM for people who are having trouble bringing their HbA1c below 8.0 and for recurrent hypoglycemia. The use of a CGM has been repeatedly shown to help improve blood sugar control and lower HbA1c values. However, as a diabetic for over 15 years, and the father of a child with diabetes since age 5 (now 21), I can tell you that long term blood glucose control is only one (albeit very important) measure of successfully managing Type 1 diabetes. Equally important measures are the ability to reduce or eliminate dangerous high blood sugars, severe low blood sugars, the forewarning of potential ketoacidosis, effective sick day management, and finally, quality of life (the ability to sleep well without worrying about undetected hypoglycemia, for instance).	Thank you for taking the time to comment.
	26	CGM use can aid in weight management and exercise by allowing more confidence that lack of eating or heavy/prolonged exercise will result in severe lows. Importantly, where the proposed guidance is concerned, these benefits are equally important to those who have consistently maintained an HbA1C below 8.0 as to those whose HbA1c is above 8.0.	Thank you for sharing your opinion. HTAS believes the importance of lowering HbA1c is greater in patients with levels > 8.0.
	27	Although hypoglycemia is rightly cited as a reason for including coverage for CGM use, the absence of recorded hypoglycemic events should not be a reason to deny coverage for those with high or low HbA1c values. First, there is good evidence that many Type 1 diabetics do not capture the occurrence of many low blood sugar events through standard blood glucose monitoring: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group - Prolonged Nocturnal Hypoglycemia Is Common During 12 Months of Continuous Glucose Monitoring in Children and Adults With Type 1 Diabetes. <i>Diabetes Care May 2010 33:1004-1008</i>	HTAS does not debate the fact that diabetes do not capture many low blood sugar events. The Cochrane review identified four studies that measured the occurrence of severe hypoglycemia. At three months, the number of events was very low, and at six and 12 months, the risk of severe hypoglycemia was actually increased for CGM users, but the difference was not statistically significant.
	28	Those who are able to successfully use a CGM to either better control their diabetes, resulting in a lower HbA1c and avoiding recurrent hypoglycemia (the two qualifying criteria), should not be dropped from coverage of CGM	The guidance does not address cessation of coverage, only

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		use due to that success.	indications for initiation.
	29	The single study referenced in the guidance focused primarily on “average blood glucose level” as expressed in the measured HbA1c. Although mentioning the importance of hypoglycemia (and an attempt to measure the occurrence) it was not deemed significant due to the low number of events which precluded their evaluation. There are other studies however, that have confirmed the benefits of CGM use in patients with well controlled glucose (HbA1c < 7.0) and in those with poorly controlled diabetes in terms of avoiding severe or prolonged hypoglycemia:	It is not clear what single study the commenter is referring to. The guidance references the Cochrane review which is a full systematic review of the evidence and includes a total of 22 studies.
	30	<p>“An additional important observation was the remarkably low rate of severe hypoglycemic events during the extension phase of the study. The rate of severe hypoglycemia in our CGM subjects with a mean A1C of 6.8% during the 6-month extension phase was markedly lower than the rate of severe hypoglycemia in the Diabetes Control and Complications Trial (DCCT) intensive treatment group, which had mean A1C of 7.1% (7 vs. 62 events per 100 person-years) (6). The total absence of severe hypoglycemia during the second 6 months of the study in the subjects who had a baseline A1C <7.0% is particularly striking, especially because these subjects were able to maintain a mean A1C of 6.4%.</p> <p>It is possible that the decline in severe hypoglycemic events during the second 6 months of the study resulted from learning from prior experience, including appropriate setting of the low alarms, glucose targets, and titration of basal and bolus insulin doses. It is also intriguing to speculate that the reduction in exposure to biochemical hypoglycemia over the 12 months of the study may have protected subjects from severe hypoglycemic events by enhancing their counterregulatory hormone defense mechanisms against hypoglycemia (7).”</p> <p>The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group - Sustained Benefit of Continuous Glucose Monitoring on A1C, Glucose Profiles, and Hypoglycemia in Adults With Type 1 Diabetes. <i>Diabetes Care November 2009 32:2047-2049</i></p>	The citations listed were published before the date of the Cochrane review (last search date June 2011). The HTAS bases their guidance documents on reviews of the literature that utilize the highest standards of evidence based medicine. Studies are included or excluded based on transparent, reproducible criteria; therefore the HTAS does not investigate individual studies. The HTAS assumes that the conclusions reached by the authors of these reviews weigh all the available evidence in accordance with the principles of evidence based medicine, and does not attempt to re-review the entire body of evidence to reach its own conclusions.
	31	<p>We are only beginning to understand all the benefits of tight glucose control and the effects of hypoglycemia on the body, and some studies point to a possible link to development of atherosclerosis.</p> <p>Marga Giménez, Rosa Gilabert, Joan Monteagudo, Anna Alonso, Roser Casamitjana, Carles Paré, and Ignacio Conget - Repeated Episodes of Hypoglycemia as a Potential Aggravating Factor for Preclinical Atherosclerosis in Subjects With Type 1 Diabetes. <i>Diabetes Care January 2011 34:198-203</i></p>	See comment #30
	32	As a CGM user for approximately 2 years, I can tell the HERC that the use of a CGM has made my day to day life with diabetes more predictable, more successful, and more enjoyable. I believe that the use of a CGM has	Thank you for sharing your

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		reduced the likelihood that I would end up in the hospital for dehydration during sick days (ketones with low blood sugar being a surprising and challenging situation to deal with) and allowed me to be a more confident and successful public servant. I believe that every person with Type 1 diabetes should be encouraged to use a CGM if they have a need, the inclination, and the motivation.	perspective.
	33	For these reasons, I believe the use of a CGM is warranted and beneficial for all with Type 1 diabetes in terms of safety, in terms of quality of life and in terms of long term health benefits and saving of health care costs. The coverage of CGM use should be possible regardless of whether one's HbA1c is above or below 8.0, or their success in avoiding (and success in documenting) recurrent hypoglycemia. Thank you for considering these comments.	Thank you for sharing your perspective.
	34	Please note there are typos on pages 2 and 4 of the proposed guidance where HbA1c is mistakenly shown as HgA1c or HgbA1c.	Thank you, typos have been corrected.
American Diabetes Association Oregon Office Portland, OR	35	The American Diabetes Association (Association) is pleased to provide additional comments to the Commission regarding the Draft Coverage Guidance on Continuous Glucose Monitoring (CGM) in Type 1 Diabetes, and to address particular questions posed by members of the Commission to the Association during the June 25 hearing. We appreciate your willingness to consider additional information from the Association before revising the Coverage Guidance for Self-Monitoring of Blood Glucose (SMBG) for Type 1 and Type 2 Diabetes, and we are pleased to respond to your request. [Comments regarding SMBG will be addressed in a separate disposition.]	Thank you for your comments.
	36	V. Comments in response to the Draft Coverage Guidance: Continuous Glucose Monitoring in Type 1 Diabetes Mellitus issued on July 10, 2012 The Association's <i>Standards of Medical Care in Diabetes – 2012</i> includes the following recommendations: <ul style="list-style-type: none"> • CGM in conjunction with intensive insulin regimens can be a useful tool to lower A1C in selected adults age 25 and over with type 1 diabetes. • Although the evidence for A1C-lowering is less strong in children, teens and younger adults, CGM may be helpful in these groups. Success correlates with adherence to ongoing use of the device. • In addition, CGM may be a supplemental tool to SMBG in those with hypoglycemia unawareness and/or frequent hypoglycemic episodes. 	HTAS believes that the current coverage guidance supports these stated standards.
	37	The revised Draft Coverage Guidance on Continuous Glucose Monitoring in Type 1 Diabetes issued on July 10 includes the following recommendation: Real time CGM systems should be covered for Type 1 diabetes mellitus patients with a history of recurrent hypoglycemia or HbA1c > 8% for whom insulin pump management is being considered, initiated or utilized. We note that research has shown benefits for CGM in individuals with type 1 diabetes on intensive insulin therapy (<i>either</i> an insulin pump or multiple daily injections). ³ Thus, we recommend adding "multiple daily insulin injections or" after the words "for whom" in the Coverage Guidance document to include individuals on multiple daily injections of insulin.	HTAS acknowledges that CGM has been shown to have a statistically significant beneficial effect on HbA1c in both insulin pump and MDI populations, however, the improvements in HbA1c are generally not considered clinically significant in the MDI patients (-

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			<p>0.30% to -0.36%), and there have been no studies that found improvements in quality of life, hypoglycemia, diabetic complications or mortality in this patient population.</p>
	38	<p>Diabetes is a complex disease to manage and can lead to short and long term complications. The goal of diabetes care is to avoid the devastating and costly complications of the disease. The costs associated with diabetes, including diagnosed and undiagnosed diabetes, prediabetes, and gestational diabetes, and their complications, accounted for \$218 billion in direct and indirect costs in 2007 alone. Much of the economic burden of diabetes is related to its complications including blindness, amputation, kidney failure, heart attack, and stroke. Yet, we have made major strides in effectively managing diabetes and reducing the risk for these devastating – and costly – complications through necessary medical care, medications and other tools, patient self-management, education, and support. We appreciate the opportunity to provide comments to the Commission as it develops Coverage Guidance documents for CGM and SMBG. The Association looks forward to reviewing the revised Coverage Guidance documents.</p>	<p>HTAS is aware of the complexity of diabetes management, and believes that the guidance as currently written provides the needed flexibility in patient management. Thank you for taking the time to provide the HTAS with this information.</p>