

HERC Coverage Guidance – Self-Monitoring of Blood Glucose for Type 1 & Type 2 Diabetes Disposition of Expert Comments

Stakeholder	#	Comment	Disposition
Farahnaz Joarder, MD Assistant Professor, Endocrinology & Diabetes, Oregon Health & Science University	1	Statement in reply to HERC Coverage Guidance: For patients with Type 2 Diabetes Mellitus not requiring insulin, home blood glucose monitors and related diabetes supplies are recommended for coverage only for those who have initial HbA1c levels greater than 8.0%, and in sufficient quantity to allow once a week testing. Such coverage should include a structured education and feedback program for self-monitoring of blood glucose (SMBG).	HTAS concurs that this is the current proposed guidance.
	2	As the prevalence and incidence of diabetes grows, there is increased attention to diabetes care, complications and cost. Self-monitoring of blood glucose is a standard practice in diabetes care that facilitates diabetes self-management. The choice and physiologic impact of type 2 diabetes treatments has changed over time with new and complex algorithms developed which help practicing providers tailor and individualize care. Prior reports demonstrated the complexity of proposed models/algorithms of treatment for patients with type 2 diabetes (1). Utilization of blood glucose monitoring facilitates decision making for patients and providers within the context of these complex treatment algorithms.	Thank you for your comment.
	3	The cost of test strips has been reported as a significant component of diabetes related costs and it is understandable, particularly given the number of people with type 2 diabetes on oral medications or other non-insulin therapies, that this cost receives scrutiny in the face of rising health care costs and challenges with health care coverage.	Thank you for your comment.
	4	The proposed HERC coverage guidance for self-monitoring of blood glucose addressed the testing of blood glucose in type 2 diabetes. The specific coverage guidance has several implications. <ol style="list-style-type: none"> 1. It suggests that only patients with an HbA1c of 8.0% would benefit from self-monitoring of blood glucose. 2. It also, conversely suggests that there is no clinical benefit in testing individuals with an HbA1c of less than 8.0%. 3. The specific coverage also implies that in the setting of testing with an HbA1c of greater than 8.0% that once weekly testing is adequate or meaningful. 4. It encourages utilization of structured education and feedback regarding testing presumably to facilitate meaningful testing in those who qualify to receive test strips. 5. The number of individuals impacted by this is significant given the prevalence of type 2 diabetes. 6. There is potential influence on the policy/coverage for individuals currently covered by other government programs and commercial insurance. 7. If put into effect, this guidance may dramatically change and hinder traditional diabetes education and limit the impact that SMBG has on changing patterns of diet and exercise. SMBG is one of the 7 key core principles of diabetes education as listed by the AADE (American Association of Diabetes Education). 	The coverage guidance is based on a large body of literature, a systematic review (Clar 2010) that included 11 systematic reviews. In all, it included 26 RCTs and 31 observational studies. This body of literature reports a clinically insignificant effect of SMBG on HbA1c overall, with some evidence of increased depression and anxiety. When SMBG is accompanied by structured education and feedback, a clinically significant improvement in HbA1c is achieved, compared to no monitoring, hence the requirement that when SMBG is utilized, it should be accompanied by structured education and feedback.

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		<ul style="list-style-type: none"> a. The AADE 7 are as follows: <ul style="list-style-type: none"> i. Skills and knowledge acquisition in key self-care areas of healthy eating ii. Physical activity iii. Glucose monitoring iv. Medication management v. Reduce risks of acute and chronic complications vi. Problem solving of diabetes care related issues vii. Psychosocial adaptation to living with diabetes 	
	5	<p>Since the Diabetes Complications and Control Trial (DCCT) and United Kingdom Prospective Diabetes Study (UKPDS), the utilization of self-monitoring of blood glucose has increasingly been accepted as a part of standard practice. The literature that reports on the utility of SMBG has been controversial. Although multiple researchers have attempted to review and study the utility of SMBG, well-designed trials that accurately assess the value of SMBG are lacking.</p>	<p>Many of the trials that were included in the Clar review were fair to good quality (total of 11 of the RCTs).</p>
	6	<p>One of the major references cited in the committee review on SMBG is a review of the literature and meta-analysis by Clar et al. in 2010 (2). The primary question articulated by these authors was whether SMBG is worthwhile in patients, or selected patients with type 2 diabetes on diet alone, metformin alone, combination oral therapy or combination of therapy and basal insulin. Outcome measures included HbA1c, hypoglycemia, quality of life, cost, treatment satisfaction, body weight, treatment change, lipids and blood pressure. The primary method of analysis was based on SMBG versus no SMBG, more intensive versus less intensive monitoring and more intensive monitoring versus no SMBG. They also looked at SMUG (self-monitoring of urine glucose). The population studied was limited to adult patients. It excluded pregnant women with diabetes, type 1 diabetes patients and individuals on complex insulin regimens.</p>	<p>Thank you for this summary of the Clar review.</p>
	7	<p>The authors very thoughtfully laid out the following important measures of consideration to help identify the utility of SMBG:</p> <ol style="list-style-type: none"> 1) Did patients receive education about SMBG? <ol style="list-style-type: none"> a. on how to test b. on how to interpret the results 2) How were the results used? <ol style="list-style-type: none"> a. For behavior change b. Treatment adjustment by the patient c. Treatment adjustment by the provider 3) What message did the patient receive from the provider? <ol style="list-style-type: none"> a. Positive - to assist the patient in gaining control of their treatment b. Negative - cause guilt associated with off range values 	<p>See comment #6</p>

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		<p>c. Did the patients get the impression that SMBG was good?</p> <p>How does benefit vary by starting HbA1c, frequency, education, susceptibility to hypoglycemia, treatment, age, time point during course of treatment of disease?</p>	
	8	<p>However, it is striking when reviewing the tables comparing the different review papers, observational studies and randomized controlled trials that there is a lack of consistency and a wide variation in studies included for review. In addition, careful review of the conclusions, recommendations and comments summarized by the authors in table 4 demonstrates a common theme of missing or limited data as it pertains to hypoglycemia, behavior change, treatment change and cost. The authors also acknowledge the lack of information on patient adherence to testing, type of education and instruction offered, and provider utilization and feedback of SMBG data for behavior change or treatment decisions. Furthermore, future recommendations and comments listed by the authors emphasize the need for more information on actual frequency of SMBG and adherence to testing. Adequate information and data to address these key measures of consideration in interpretation of SMBG is essential to making appropriate conclusions. The quality of the majority of the clinical trials reported in this paper by Clar et al. has come into question by reviewers with 15 listed as poor quality, 7 as fair in quality and 4 of good quality. Even those studies that are considered of good quality are of limited value if they do not adequately address and measure the relevant key measures for assessment of the utility of SMBG.</p>	<p>HTAS does not disagree that the evidence does not address all of the desired outcomes. It is, however, a substantial evidence base that is able to indicate the effect of SMBG on HbA1c, the intermediate outcome most commonly used for assessment of diabetes control.</p>
	9	<p>The outcome measure most consistently reported in review studies is HbA1c. The final result of the meta-analysis by Clar et al. on overall impact of SMBG versus no SMBG in 10 randomized controlled trials demonstrates a significant -0.21% reduction in HbA1c. Additionally noted by the authors of this review was a trend toward reduction in HbA1c in those studies that included an educational component. With more accurate data on individuals who were adherent to SMBG and were also given appropriate instruction and feedback on SMBG, an even more significant reduction might have been observed.</p>	<p>HTAS agrees with this comment.</p>
	10	<p>In the time following the Clar et al publication, the controversy over SMBG testing in non-insulin treated diabetes has continued and has triggered expert opinion response. In July 2011 the Coalition for Clinical Research–Self-Monitoring of Blood Glucose Scientific Board convened a meeting in San Francisco to discuss current practice of SMBG in non-insulin treated type 2 diabetes patients (3). The authors of this review reinforce that for SMBG to be effective there must be patient and provider education, structure in testing and a system of feedback and guidance on treatment. In addition, the authors point out common design flaws in prior trials and state the need for additional well-defined studies to assess the benefits and costs of SMBG with end points not limited to HbA1c. Common design flaws in SMBG trials include small sample size, selection of subjects with low baseline HbA1c, lack of data on adherence to testing, lack of data on frequency of testing, lack of patient instruction on testing, lack of guidance on response to SMBG data, and lack of utilization of the SMBG data by the provider. In addition, SMBG is not a uniform intervention like medication (4). Rather, SMBG is a tool for intervention, and the impact of the intervention varies depending on the frequency and timing of the testing, the clinical context</p>	<p>Expert opinion is the lowest level on the hierarchy of evidence; a well conducted SR will provide less biased information. With regard to the flaws cited by this expert group, sample size was over 100 in a majority of the 26 trials (largest trial 800), and mean HbA1c was over 8 in a majority of trials.</p>

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		and the meaningful utilization of SMBG by the patient and the provider.	
	11	In 2012 another comprehensive review on self-monitoring of blood glucose on non-insulin treated type 2 diabetes patients was published (5). The authors report a significant HbA1c reduction of 0.3 at 6 months in their meta-analysis but a statistically insignificant reduction at 1 year (5). This publication triggered additional point-counter-point discussion on the controversy of SMBG testing (4). It is worth noting that three studies that were excluded from this review demonstrated a positive impact of SMBG on HbA1c.	This is also a Cochrane review that confirms the findings of the Clar review, that SMBG results in a clinically insignificant decrease in HbA1c (0.26), and further finds that this small change becomes statistically insignificant by 1 year. The only subgroup analysis they were able to complete was for duration of disease, which found that for newly diagnosed type 2 diabetics, SMBG resulted in both a clinically and statically significant decrease in HbA1c at 1 year (0.52). <i>For HTAS discussion</i>
	12	First, the Structured Testing Program (STeP) study evaluated the utility of structured testing and feedback with SMBG (6). Patients in the intervention group received training on how to test and how to identify and address problematic glycemic patterns. These patients were instructed to utilize a 7-point SMBG testing profile (fasting, preprandial, 2 hours postprandial and bedtime SMBG). In contrast, those in the usual care group were provided test strips but no additional instruction or feedback. After 1 year, participants in the intervention group demonstrated an overall 0.3% reduction in HbA1c; an even greater reduction of 0.5% was notable among those who were identified as adherent. This study highlights the utility of pairing structured education and feedback with SMBG.	This trial was excluded because the control group used SMBG as well as the intervention group.
	13	Second, in the ROSES Study Group trial, participants in the intervention group were assigned a self-monitoring-based disease management strategy that centered on modification of lifestyle according to SMBG. After 6 months, significantly greater reduction in HbA1c (0.5% reduction) was observed in the intervention group compared to usual care (7). This study highlights the potential benefit of SMBG in impacting behavior and lifestyle modification.	This trial was excluded because it was not randomized.
	14	Third, the St. Carlos trial evaluated the impact of SMBG in newly diagnosed type 2 diabetes patients. The intervention in this study focused on utilizing SMBG as a tool for step-by-step lifestyle and pharmacological decision-making; in contrast, treatment decision in the control group was based strictly on HbA1c. After 1 year of follow-up the median HbA1c and BMI were both significantly reduced in the intervention group compared to the control group (8).	This trial WAS included.

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	15	On a practical level, especially in the context of health care reform, one must consider the cost of diabetes care and the cost effectiveness of SMBG. The data on cost effectiveness of SMBG are varied and conflicting. One cost effectiveness study utilizing a Markov model demonstrates an increase in life expectancy and reduced cost of complication with SMBG (9). Another cost effectiveness study performed at Kaiser Permanente suggested that routine testing (daily or three times daily) was associated with reduced risk of complication even though there was no cost savings (10). Although other studies do not show cost effectiveness of SMBG (2) these studies are faced by the same limitations faced by studies reviewing the efficacy of SMBG. It is therefore difficult to make a reasonable conclusion about the cost effectiveness of SMBG as an individual intervention.	The Kaiser study based estimates of effectiveness on three SRs all of which were published before the date of Clar. Reference 9 is a letter, unable to evaluate study characteristics or quality, but it was published before the date of the Clar review. The Clar review states that the best quality economic review is Farmer 2009, which concluded that SMBG was not cost-effective.
	16	Recent reports estimate that the total cost of diagnosed diabetes in 2012 is \$245 billion, including \$176 billion in direct medical costs and \$69 billion in reduced productivity (11). It has been estimated that forty-three percent of the total medical cost is attributed to hospital inpatient care costs. As reported recently in Diabetes Care, general medical conditions and cardiovascular disease are responsible for 78% of hospital inpatient costs attributed to diabetes. Investment in disease prevention is essential to bring about a reduction in the morbidity and mortality associated with diabetes. This investment in prevention is essential for cutting costs in the long term. Investment in diabetes education is an important means to invest in prevention and reduction of long-term health care costs. Although upfront costs may be higher, prior studies have reported that individuals who receive diabetes education have lower claims for inpatient hospital stays compared to those who do not receive diabetes education (12). SMBG is a key component of diabetes education, and the expense of SMBG can be viewed as an investment in prevention.	Ref #12 is a retrospective database study using claims data, a study type highly susceptible to bias. As noted above, the Clar review concludes that SMBG is not cost-effective.
	17	Unfortunately, we are faced with a challenging health care policy decision in a setting of conflicting data and the need for additional well-designed studies that evaluate the benefits and cost of SMBG. The American Diabetes Association Professional Guidelines support use of SMBG as a guide for individualized management and assessment of postprandial glucose. The guideline supports patient education on SMBG technique and interpretation of data.	The ADA guideline has the following recommendations pertaining to SMBG: “For patients using less-frequent insulin injections, noninsulin therapies, or medical nutrition therapy (MNT) alone, SMBG may be useful as a guide to management. (E)” AND To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)

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			(E) refers to the evidence supporting the recommendation, which is expert opinion.
	18	The current Medicare guideline for coverage is coverage for 100 test strips in 90 days.	HTAS is aware of this.
	19	For many physicians SMBG is standard practice and a natural tool for diabetes care. It is worthwhile to briefly review the clinical relevance of SMBG in day-to-day practice. SMBG permits identification of an individual's glycemic pattern over a 24-hour period, which is unique in comparison to the three-month average estimated by the HbA1c (13). In the management of type 2 diabetes, the structure, duration and frequency of testing is individualized based on the questions raised and the clinical context. Structured testing protocols such as paired testing of blood glucose before and after meals and 7-point testing (fasting, before meals, 2 hours after meals) allows real time assessment of response to changes in diet, activity and medication. Testing over a defined period of time allows identification of a meaningful pattern that can be utilized to guide specific changes in management.	There are many elements of standard practice that are not based on evidence. If testing ultimately has no significant effect on blood sugar control, but may lead to increased depression/ anxiety as indicated by the evidence, it is not helpful.
	20	Utilization of glucose monitoring, for example, can facilitate and reinforce appropriate choices with diet and activity. Conversely, SMBG can provide tangible and immediate feedback on the impact of poor dietary choices and reduction in physical activity. In addition, SMBG data can provide specific feedback and facilitate development of an optimal treatment plan in patients newly diagnosed with diabetes or in patients with changing therapy. Also, persistent unexplained new onset hyperglycemia revealed through SMBG testing may be a sign of stress, illness or infection. In addition, SMBG is a tool for recognition of hypoglycemia and evaluation of response to treatment of hypoglycemia. Monitoring of blood glucose may be particularly critical for patients who are elderly, have long duration of diabetes, have coronary artery disease, microvascular complications or other high risk comorbid health conditions. In review of lessons learned from the ACCORD trial, where hypoglycemia has been proposed as a mediating cause of excess mortality (14), individualized and careful attention to the glycemic trends and the responses to medication changes in high risk patients is warranted.	Of note, the Clar review noted a decreasing uptake of glucose test strips with increasing age. Ref #14 is a narrative review of the ACCORD trial, among others, which showed that tighter control of type 2 diabetics resulted in improved microvascular outcomes but increased mortality.
	21	As a clinician, utilization of SMBG is a meaningful part of my office visit. It is a tool I use routinely to make appropriate decisions on treatment. It is a tool that helps me engage my patients in their care. I review glucose meter downloads with patients as a point of discussion, and try to help patients understand their response to changes in diet, activity, stress, illness and new medication. In addition, I utilize SMBG as a tool for safety for those individuals who are at risk for hypoglycemia. My utilization of SMBG data for diabetes care is not unique. My recommendation for frequency of testing and duration of testing is specific to the individual needs of the patient. I agree, as the literature suggests, that SMBG is of greatest benefit if there is education, structure and feedback in which both the patient and the provider can have a meaningful exchange as it pertains to glucose monitoring data. My recommendation to the committee is, that if the commitment is made by the provider to provide education, structure and feedback on SMBG, that the provider in turn be allowed the choice to	See comment #19

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		determine the specific testing frequency and duration of testing that is appropriate for a given patient.	
	22	<p>With regard to the HERC coverage guidance for non-insulin dependent type 2 diabetes patients I suggest the following be considered:</p> <ol style="list-style-type: none"> 1) Elimination of the restriction of testing once weekly and removal of a cutoff HbA1c 2) Continuation of the current Medicare Guidelines for 100 test strips provided over a 90 day period. If this is not possible, consider automatic coverage for 90 days to all patients every year with one refill regardless of HbA1c. This would minimize undue burden of processing requests for coverage on the part of the provider and insuring agencies. Consider requiring provider documentation that supports SMBG testing for additional refills. 3) Consideration for exceptions to the rule if the current Medicare guideline is not maintained. Examples of patients to be considered for exception to the rule: <ol style="list-style-type: none"> a. Patients newly diagnosed b. Patients changing treatment c. Patients on insulin secretagogues d. Patients with history of hypoglycemia e. Elderly patients f. Patients with multiple comorbid conditions or microvascular or macrovascular complications of diabetes g. Patients with gestational diabetes or diabetes in pregnancy 	The guidance does not address SMBG in gestational diabetics. HTAS does not believe these suggestions comport with the evidence.
	23	<p>I thank the committee for their time and review of this topic. I appreciate the opportunity to provide my perspective.</p> <p>References:</p> <ol style="list-style-type: none"> (1) Rodbard HW, Jellinger PS, Davidson JA, Einhorn D, Garber AJ, Grunberger G, Handelsman Y, Horton ES, Lebovitz H, Levy P, Moghissi ES, Schwartz SS; Statement by American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 diabetes mellitus: an algorithm for glycemic control, <i>Endocr Pract.</i> 2009; 15(6):540-59 (2) Clar C, Barnard K, Cummins E, Royle P, Waugh N; Aberdeen Health Technology Assessment Group. Self-monitoring of blood glucose in type 2 diabetes: systematic review. <i>Health Technol Assess.</i> 2010; 14(12):1-140. (3) Klonoff DC, Blonde L, Cembrowski G, Chacra AR, Charpentier G, Colagiuri S, Dailey G, Gabbay R, Heinemann L, Kerr D, Nicolucci A, Polonsky W, Schnell O, Vigersky R, Yale J-F, Consensus Report: The Current Role of Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes, <i>J Diabetes</i> 	Thank you for your input.

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		<p>Science and Technology, 2011; 5(6).</p> <p>(4) Polonsky W, Fisher L, Self Monitoring of Blood Glucose in Non-insulin Dependent Type 2 Diabetic Patients: Right answer, but wrong question: self monitoring of blood glucose can be clinically valuable for noninsulin users, <i>Diabetes Care</i> 2013; 36, 179-182.</p> <p>(5) Malanda UL, Welschen LM, Riphagen II, Dekker JM, Nijpels G, Bot SD, Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin, <i>Cochrane Database Syst Rev</i>, 2012; Jan 18.</p> <p>(6) Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, non-insulin treated type 2 diabetes: results from the Structured Testing Program study. <i>Diabetes Care</i> 2011; 34(2):262-7.</p> <p>(7) Franciosi M, Lucisano G, Pellegrini F, Cantarello A, Consoli A, Cucco L, Ghidelli R, Sartore G, Sciangula L, Nicolucci A; ROSES Study Group. ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial. <i>Diabet. Med.</i> 2011; 28(7):789-96.</p> <p>(8) Duran A, Martin P, Runkle I, Perez N, Abad R, Fernandez M, Del Valle L, Sanz MF, Calle-Pascual AL. Benefits of self-monitoring blood glucose in the management of new-onset type 2 diabetes mellitus: the St Carlos Study, a prospective randomized clinic-based interventional study with parallel groups. <i>J Diabetes</i>. 2010; 2(3):203-11.</p> <p>(9) Neeser K, Erny-Albrecht K, Weber C, Cost-effectiveness of self-monitoring of blood glucose in type 2 diabetes patients not receiving insulin: response to Davidson. <i>Diabetes Care</i> 2006; 29:480</p> <p>(10) Tunis SL, Minshall ME, Self-monitoring of blood glucose in type 2 diabetes: cost-effectiveness in the United States. <i>Am J Manag Care</i> 2008; 14:131-140</p> <p>(11) American Diabetes Association, Economic Costs of Diabetes in U.S. in 2012, <i>Diabetes Care</i> Publish Ahead of Print, online March 6, 2013.</p> <p>(12) Duncan I, Birkmeyer C, Coughlin S, Li Q, Sherr D, Boren S, Assessing the Value of Diabetes Education, <i>Diabetes Educator</i> 2009; 35(5).</p> <p>(13) Boutati E, Raptis S, Self-Monitoring of Blood Glucose as Part of the Integral Care of Type 2 Diabetes, <i>Diabetes Care</i> 2009; 32(Suppl. 2):S205-S210.</p> <p>(14) Riddle MC, Karl DM, Individualizing Targets and Tactics for High-Risk Patients with Type 2 Diabetes, Practical lessons from ACCORD and other cardiovascular trials, <i>Diabetes Care</i> 2012; 35:2100-2107.</p>	

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Registered Nurse, Diabetes Educator Eugene, OR	1	<p>I am writing on behalf of my colleagues at Cascade Health Solutions, Diabetes and Nutrition Education Program in Eugene, Oregon and to advocate for our patients with type 2 diabetes regarding the proposal to limit SMBG testing supplies for those with an A1C reading greater than 8% and coverage limited to testing blood glucose once weekly.</p> <p>As diabetes educators who work with persons with type 2 diabetes on a daily basis, we find one of the strongest motivators for our patients to take control of their diabetes is seeing firsthand the cause and effect of diet, exercise, medication, and stress on their blood glucose. To wait for an A1C to be 8% or above, then limit testing to once weekly invites complacency and frankly sends the message of “why bother?” We are strongly opposed to this proposal.</p> <p>I am including a link to the American Association of Diabetes Educators position statement regarding self monitoring of blood glucose and urge you to read it. http://www.diabeteseducator.org/export/sites/aade/_resources/pdf/research/SelfMonitoring2010.pdf</p>	Thank you for your comment. HTAS appreciates the perspective you bring with regard to diabetic education, but finds the evidence of lack of effect of SMBG on patient outcomes more compelling.
American Diabetes Association Seattle, WA	2	<p>The American Diabetes Association (Association) is pleased to provide comments to the Commission regarding the Draft Coverage Guidance: Self-Monitoring of Blood Glucose for Type 1 & Type 2 Diabetes posted on February 28, 2013.</p> <p>Background</p> <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. For care of patients with diabetes, treatment must be comprehensive and individualized. Diabetes affects individuals very differently and it is critically important people with diabetes have access to the type and amount of diabetes testing supplies that meet their particular needs. Self-monitoring of blood glucose (SMBG) is a component of effective therapy which allows patients to evaluate their individual response to therapy and assess whether glycemic targets are being achieved. Results of SMBG can be useful in preventing hypoglycemia and adjusting medications (particularly prandial insulin doses), medical nutrition therapy and physical activity. The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient.</p>	Thank you for your comment. However, the evidence does not support the efficacy of SMBG to achieve clinically important improvement in outcomes in type 2 diabetics.
	3	<p>Clinical Guidelines</p> <p>The Association’s <i>Standards of Medical Care in Diabetes – 2013</i> addresses the importance of assessing the effectiveness of an individual’s diabetes management plan on glycemic control through patient SMBG or interstitial glucose, and A1C. In particular, the <i>Standards of Medical Care in Diabetes – 2013</i> includes the following recommendations:</p> <ul style="list-style-type: none"> Patients on multiple-dose insulin (MDI) or insulin pump therapy should do SMBG at least prior to meals and snacks, occasionally post-prandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving. 	The coverage guidance recommendation is in alignment with the first and third bullets quoted by the commenter. With regard to diabetics using insulin less frequently or noninsulin therapies, the quoted recommendations state “SMBG results may be helpful,” suggesting an understanding of the lack of evidence to support this recommendation.

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		<ul style="list-style-type: none"> When prescribed as part of a broader educational context, SMBG results may be helpful to guide treatment decisions and/or patient self-management for patients using less frequent insulin injections or noninsulin therapies. When prescribing SMBG, ensure that patients receive ongoing instruction and regular evaluation of SMBG technique and SMBG results, as well as their ability to use SMBG data to adjust therapy. 	
	4	<p>Comments on Patients with Insulin-Requiring Diabetes Mellitus</p> <p>We strongly support the provision in the Draft Coverage Guidance which allows for coverage of home blood glucose monitors and related diabetic supplies for patients with insulin-requiring diabetes mellitus. SMBG is especially important for patients treated with insulin to monitor for and prevent asymptomatic hypoglycemia and hyperglycemia. The recommendations for glucose monitoring in the Association’s <i>Standards of Medicare Care in Diabetes – 2013</i> were revised from the previous year to highlight the need for patients on intensive insulin regimens to do frequent SMBG. Most patients with type 1 diabetes and others on intensive insulin regimens (multiple-dose insulin or insulin pump therapy) should do SMBG at least prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.</p>	Thank you for your comment.
	5	<p>We are concerned the coverage guidance raises some uncertainty whether individuals with type 2 diabetes on less than multiple daily insulin injections are included in the recommendation for coverage of home blood glucose monitors and related diabetic supplies for individuals with insulin-requiring diabetes mellitus. For these individuals, as well as for all patients with diabetes, the frequency and timing of SMBG should be dictated by the particular medical needs and goals of the patient. The individual’s clinical situation is a critical consideration – a stable situation versus a dynamic situation will have different SMBG needs. Individuals using less frequent insulin need to perform SMBG during the course of a week to guide treatment. The optimal frequency of SMBG for patients on non-intensive regimens, such as those with type 2 diabetes on basal insulin, is not known, although all studies have used fasting SMBG for patient or provider titration of the basal insulin dose. As such, we recommend coverage of home blood glucose monitors and related diabetic supplies for patients with type 2 diabetes mellitus on less than multiple daily insulin injections. In the Draft Coverage Guidance recommendation, this could be achieved by taking out the words “multiple daily” as follows:</p> <p>For patients with insulin-requiring diabetes mellitus, including those with Type 2 diabetes using multiple-daily insulin injections, home blood glucose monitors and related diabetic supplies are recommended for coverage and should include a structured education and feedback program for self-monitoring of blood glucose.</p>	<p>The evidence source for the guidance (Clar 2010) included some studies of type 2 diabetics on basal insulin. Of the 26 included RCTs, 7 could include patients on basal insulin, and 5 did not report what treatments patients received. Therefore, the coverage guidance does not exclude patients with type 2 diabetes on basal insulin.</p> <p><i>For HTAS discussion</i></p>
	6	<p>Comments on Patients with Type 2 Diabetes Not Using Insulin</p>	In the Clar 2010 review, 7 of the 26 RCTs

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		The Draft Coverage Guidance states that, for patients with Type 2 diabetes mellitus not requiring insulin, home blood glucose monitors and related diabetic supplies are recommended for coverage only for those who have initial HbA1c levels greater than 8.0%, and in sufficient quantity to allow once a week testing. SMBG provides vital information concerning extremes of glucose. As treatment is initiated, SMBG can be useful to identify the trajectory of the disease in that individual and his/her response to treatment. The testing frequency should be based on the recommendations of the physician. We urge you to also consider that individuals on sulfonylurea therapy are at risk for hypoglycemia, particularly when their HbA1c is well controlled. Thus, the HbA1c cutoff of 8% would exclude those on sulfonylureas with greatest need for SMBG to protect them from hypoglycemia. Additionally, SMBG during times of acute illness is critical to identify dangerous decompensation of glucose, either diabetic ketoacidosis or hyperosmolar nonketotic states, even in those individuals otherwise in good glycemic control. The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient and the recommendations of the treating clinician for that particular patient. The Association strongly recommends, if coverage limits are set for diabetes testing supplies, an exceptions process be provided based on individual circumstances. Such a process should not be overly burdensome on the patient or clinician.	reported on hypoglycemic events. Results were inconsistent, but suggested that hypoglycemic events were increased with more frequent monitoring. <i>For HTAS discussion (exceptions process)</i>
	7	Structured Education and Feedback Program We applaud the Commission for continuing to include coverage for a structured education and feedback program for SMBG in the Draft Coverage Guidance.	Thank you for your comment.
	8	Diabetes is a complex disease to manage and can lead to short term and long term complications, such as blindness, amputation, kidney failure, heart attack and stroke. 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. Thank you for the opportunity to comment on the Draft Coverage Guidance.	Thank you for your comment.
<i>Physician, Professor of Medicine,</i>	9	The purpose of my letter is to submit comments on the HERC preliminary determination on self-monitored blood glucose. My comments will be restricted to the specific portion addressing those with type 2 diabetes who not on insulin. I fully endorse the recommendations on SMBG for those treated with insulin.	Thank you for taking the time to comment.
<i>Director of a Diabetes Health Center Portland, OR</i>	10	Please note that I support evidence-based medicine. I was the chair of the Oregon Diabetes Guidelines Committee for three iterations over a decade and I served for 2 years on the American Diabetes Association Professional Practice Committee that defines the national ADA standards of care. Both of these efforts have been predicated on scientific evidence. In recent years when evidence based medicine has often meant annotation of numerous studies performed on different populations with different primary end-points and different clinical approaches by individuals who have limited expertise in the clinical practice affected, I have become concerned about the conclusions that are rendered. Such is the case for SMBG. I readily admit there is no good evidence supporting routine, unrestricted use of SMBG in those not on insulin. However, “lack of evidence” does not mean “lack of benefit”, particularly when the	Thank you for sharing your background and your concurrence that “there is no good evidence supporting routine, unrestricted use of SMBG in those not on insulin”. HTAS agrees that it is useful to examine efficacy in subgroups. The Clar review specifically attempted subgroup analysis when data was sufficient. They found clinically important improvements

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		process represents an impossible task of making sense of literature that is usually designed to answer a simple question of whether blanket testing in this group is beneficial as measured by HbA1c. The evidence shows that the answer to that question is “no”. It is here that we see the weakness of an evidence-based process that fails to ask more questions or accept contingencies. The new question should be “is there a value to SMBG when used properly in certain subgroups and should we exclude this coverage from all patients in the category in question?” Certainly the goal is to determine where is testing valuable rather than to use a technicality to bluntly say “there is no value”.	in HbA1c when SMBG was accompanied by structured education and feedback, and when baseline HbA1c was >8, hence the coverage recommendation.
	11	Careful review of any of the numerous meta-analyses such as that of Clar et al demonstrates the inconsistencies of those approaches (different studies included very various authors) but Clar points out that important details are missing from virtually all of those studies preventing one from making firm conclusions, particularly with regard to best methods, most appropriate populations and avoidance of hypoglycemia. That final issue of hypoglycemia is a very real consideration given the results of the ACCORD trial that resulted in changes in the ADA/EASD treatment guidelines for type 2 diabetes with very much heightened concern about all agents that cause this including sulfonylureas (SUs). Of course, the concern of hypoglycemia with SUs is most relevant in those well controlled, not those who are poorly controlled.	While firm conclusions cannot be drawn on all aspects of the evidence, the Clar review does reach the following conclusion: “The evidence suggested that SMBG is of limited clinical effectiveness in improving glycaemic control in people with T2DM on oral agents, or diet alone, and is therefore unlikely to be cost-effective”. With regard to hypoglycemia, see comment #6.
	12	If one accepts that large meta-analyses dilute and confuse the selective benefit of SMBG in specific circumstances, we then have to take some guidance from recent, more directed studies and to some degree from expert opinion. For example, Polonsky et al demonstrated that structured glucose testing had benefits over unspecified testing, reducing the A1c by 0.5% in those who adhered to the plan and 0.3% overall. In the ROSES study, Franciosi et al demonstrated that a lifestyle modification approach guided by SMBG reduced A1c by 0.5%. Most recently the 3-year results of the St. Carlos study confirmed a 4.5 fold increase in the number of type 2 patients on metformin who reached an A1c < 6.0% when they used SMBG vs using A1c alone for guidance. Garcia de la Torre et al performed this well-done randomized prospective trial and it is now published online in advance of print.	HTAS does not agree that large meta-analyses dilute and confuse the benefits of SMBG. In the Polonsky study, funded by Roche, the intervention utilized the “Accu-Chek 360° View blood glucose analysis system (Roche Diagnostics), a validated tool that enabled patients to record/plot a 7-point SMBG profile (fasting, preprandial/2-h postprandial at each meal, bedtime) on 3 consecutive days prior to each scheduled study visit (months 1, 3, 6, 9, and 12)”. Using this intervention, this would entail use of only 105 test strips over the year, or fewer than 9/month. This was accompanied by education and instruction, while the control group

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			<p>received strips, but no instructions. Frequency of testing was not different between groups, hence this study does not address the question of whether testing is better than no testing. Instead, this study demonstrates the value of structured education and feedback, not of SMBG alone.</p> <p>The ROSES study was a small pilot (n=62) where SMBG was combined with intensive education by diabetic nurses, including monthly phone calls, and entailed SMBG only 12 times per month. The intervention group lost significantly more weight than the control, and is likely what led to the improvement in HbA1c. Unclear what the contribution of SMBG over nurse management was.</p> <p>The St. Carlos study was limited to recent diabetics, with average baseline HbA1c of 6.7. The metric measured was the number in the intervention group who “regressed” (HbA1c <6%). Given current evidence of the dangers of tight control for T2DM (ACCORD trial), unclear what the value of this is for patient important outcomes.</p>
	13	This mounting evidence indicates that there is benefit from SMBG for some type 2 patients not on insulin when done with adequate education, when reviewed and discussed by providers, and particularly with motivated patients. There is relatively strong support for SMBG as an educational tool as is now the practice in every nationally recognized diabetes education program.	The 3 studies cited do not negate the findings of the large body of evidence in the Clar review.
	14	The guidance for the HERC indicates that “a weak recommendation is indicated where further research is very likely to have an important impact on our confidence in the estimate of effect”. Given that guidance, I request the subcommittee attempt to mitigate the impact of its present recommendation.	Unclear over what timeframe the 100 strips is recommended. Development of an authorization form is

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		<p>Some possibilities might be:</p> <ul style="list-style-type: none"> • Provision of 100 strips for all patients when they are receiving diabetes education to properly educate them on the lifestyle benefits and determine the effect of therapeutic changes. • Development of an authorization form to be used beyond the initial 100 strips to be filled out by the provider, indicating why strips are requested for a specific patient, the plan of use, the documentation of appropriate use by copies of logs or downloads along with verification that the results were reviewed with the patient. Some consideration should be given to those patients on SUs or similar hypoglycemia agents, particularly when well-controlled or when the patient has significant cardiovascular risk. • All patients with diabetes and pregnancy or gestational diabetes require monitoring and should specifically included for regular monitoring. 	<p>an implementation issue and beyond the scope of this guidance. Guidance specifically states that it does not apply to pregnant women.</p>
	15	<p>Other things to consider are special situations such as:</p> <ul style="list-style-type: none"> • Monitoring more closely at times of change in therapy • Monitoring at times of significant illness or steroid use where severe hyperglycemia can result and require immediate intervention • Monitoring when driving, particularly with passengers or commercially when on SUs. <p>I thank the committee for their service to Oregon and consideration of my comments.</p> <p>References:</p> <p>Clar C, Barnard K, Cummins E, Royle P, Waugh N; Aberdeen Health Technology Assessment Group. Self-monitoring of blood glucose in type 2 diabetes: systematic review. <i>Health Technol Assess.</i> 2010; 14:1-140.</p> <p>Franciosi M, Lucisano G, Pellegrini F, Cantarello A, console A, Cucco L, Ghidelli R, Sartore G, Sciangula L, Nicolucci A. ROSES Study Group. ROSES: Role of self-monitoring of blood glucose and intensive education in patients with type 2 diabetes not receiving insulin. A pilot randomized clinical trial. <i>Diabet Med</i> 2011; 28:789-96.</p> <p>Garcia de la Torre N, Durai A, Eld Valle L, Fuentes M, Barca I, Martin P, Montanez C, Perex-Ferre N, Abad R, Sanz F, Galindo M, Rubio MA, Calle-Pascual AL. <i>Acta Diabetol</i> 2013 online March 27th</p> <p>Inzucchi SF, Bergenstal RM, Buse JB, Diamant M, et al. Management of Hyperglycemia in Type 2 Diabetes: A patient-centered approach. <i>Diabetes Care</i>; 2012; 35: 1365-1374.</p> <p>Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parking CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS. Structured self-monitoring of blood glucose significantly reduces A1c levels in poorly controlled, non-insulin treated type 2 diabetes: results from the Structured Testing Program study.</p>	<p><i>For HTAS discussion</i></p>

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		Diabetes Care 2011; 34:262-7.	
<i>Registered Nurse, Diabetes Educator</i> Portland, Oregon	16	I was recently alerted to the possible changes that HERC has deemed appropriate when it comes to blood glucose testing. This appears to be the same argument presented in 1992 by the ADA Post Graduate Conference in Seattle Washington. Same studies, same outcomes, same argument. Studies do not reveal the true and everyday stories of lifestyle changes, empowering that individual with diabetes to take command of their disease by using a blood glucose monitor. The simple fact is that blood glucose monitoring does make a difference.	HTAS is unfamiliar with the 1992 ADA Post Graduate Conference, but is using a 2010 SR as its evidence source, so newer studies are included.
	17	I have been an RN CDE for over 22 yrs. Working with those individuals diagnosed Type 1 and Type 2 diabetes of all ages. I cannot imagine anyone with a diagnosis of diabetes not having the opportunity to check blood glucose levels. Most of us in the trenches working closely with those who have diabetes find it helpful to check blood glucose levels multiple times a day, even with a new diagnosis and an A1C < 7 %.	While anecdotal experience has a strong influence on individual opinion, it is inherently susceptible to bias. The evidence examined by HTAS demonstrates a lack of efficacy of SMBG in T2DM.
	18	Understanding foods impact on blood glucose levels, stress, when sick, how medication affects those BG levels, exercise and more. These are all reasons for performing blood glucose tests. The opportunity to self-manage daily diabetes care with or without oral agents, with or without injectable will be blinded by not having the opportunity to check blood glucose levels. Educators use blood glucose monitoring as an important visual tool for teaching lifestyle changes. "Seeing is believing", by not seeing the changes in blood sugars before and after a meal for many means nothing, they do not realize how high blood glucose levels climb. Diabetes has been labeled the silent killer. You will be handicapping every ADA, AADE certified Diabetes program in the USA. The individuals that will be impacted the most have more than one co morbidity.	See comment # 17. This guidance document applies only to Oregon, not the entire USA.
	19	Your decisions and recommendations of who can and cannot check BG levels will ultimately guarantee those with diabetes more visits to the emergency room, higher risks of complications. In our world now of higher cost to manage disease states you are removing the cheapest most efficient way that someone has of managing their own diabetes care.	See comment #11. There is no evidence that SMBG is cost-effective for T2DM.
	20	Relying on the A1C test is not the answer. There are inaccuracies with this test: Kidney issues, anemia, and investigating patterns of hypoglycemia, hyperglycemia (especially in the elderly) are examples of problems that will prevent physicians, educators in assaying the right and proper diabetes treatments. I believe that removing the opportunity to monitor blood glucose levels is a tremendous blow in diabetes self-management. We all know that the diagnosis of diabetes continues to grow. We understand that as the population ages more complications are associated with diabetes at the start. One doesn't develop diabetes overnight.	See comment #17. There is no evidence that lack of SMBG leads to more complications or ER visits in T2DM.
	21	I so hope that you will reconsider this decision. The cost of Diabetes will go higher, more ED visits, more risk of complications and caring for a sicker population is not cost effective. There will be higher costs due	See comment #20

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Stakeholder	#	Comment	Disposition
		to this unwise move. Obviously, Diabetes Educators are a very compassionate group that are dedicated to our patients and the world of diabetes. I hope that you will reconsider this unwise move. Thank you for your time on a very serious matter.	
Registered Dietician, Diabetes Educator Oregon	22	I am writing to oppose a proposal to limit glucose monitoring for patients with Type 2 diabetes to once a week. I do support controlling how many tests are needed for type 2 Diabetes not on insulin. I manage a lot of patient with Type 2 diabetes on one test per day. Please don't limit the glucose tests to less than once a day. The testing does provide immediate and important feedback for patients with diabetes and can be crucial in identifying sudden worsening of diabetes control. If a patient is able to monitor and take action earlier, in some cases a visit to the emergency room or hospital can be avoided thereby saving money. Let's not be penny wise and pound foolish.	Thank you for your comment and your interest in controlling costs. Unfortunately, the evidence does not support the effectiveness of SMBG for T2DM when not accompanied by education and feedback, or when HbA1c < 8.0. In addition, testing more frequently than once a week was found no more effective than once weekly testing.
	23	I am in favor of leaning on the blood glucose monitoring industry to get lower cost testing, it is a racket (test strips for all major brands are still \$1 per test which has been the case for 15 years or more! At least for our OHP and Medicare, negotiate a price on 1 or 2 meters to save us all some money! Once a day testing can work for non insulin using Type 2 Diabetes, but once a week testing is not sufficient.	Thank you for this interesting idea, but it is beyond the scope of this guidance. See comment #22.
Adult Nurse Practitioner, Diabetes Health Center Portland, OR	24	I am writing about the new proposed guidelines for blood glucose testing for patients with type 2 diabetes on oral therapy. I have worked in diabetes exclusively for 10 years and have diabetes myself. Quite frankly, I am aghast at the proposed changes to testing guidelines. Blood glucose testing is a vital part of taking care of patients with diabetes for both providers, patients and their families and/or caregivers. Medication regimens are changed frequently, patients have lifestyles which change, illness comes which all can affect diabetes control positively or negatively. The only way to know how these things affect glucose control is to test at least on a daily basis. Once weekly testing tells the patient and provider nothing and might as well not be done.	Thank you for your comment. HTAS disagrees that SMBG is the only way to know how a variety of factors affect glucose control; HbA1c is a standard, commonly used measure. In addition, the evidence does not support the efficacy of SMBG without education and feedback, and unless the HbA1c is ≥ 8.0.
	25	Generic test strips are available for \$36 per 100 which is only about \$33/month for once daily testing. Admittedly, some patients do not need to test, but for those who do, this is a small price to pay to prevent both short and long term complications. My hands would be tied in caring for my patients without glucose testing. I certainly do not need to spend more time doing prior authorization requests. Please do not take this important guide away!	The exact cost of strips varies based on contracting issues and is beyond the scope of this guidance. At \$33/month, annual costs would be nearly \$400, and given the prevalence of T2DM, this results in substantial costs, especially if the intervention is ineffective.
Registered Nurse, Diabetes	26	I am writing to you on behalf of a proposal I heard about which is a recommendation from the Oregon Health Policy and Research division of the Oregon Health Authority. I have been a certified diabetes educator in the state of Oregon for over 27 years and work full time in an outpatient/inpatient hospital	Thank you for your comment. The question is not what the appropriate HbA1c target is, but whether SMBG is

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Educator Albany, Oregon		setting. The proposal of limiting SMBG testing supplies for people with Type 2 diabetes ONLY for those patients with an A1c greater than 8 % is absolutely ludicrous! An A1c result of 8% is not the target endorsed by the American Diabetes Association or ACE, American College of Endocrinology. Not only is this recommendation dangerous and unsafe, but to consider covering supplies for persons who have diabetes for only once a week blood glucose testing is even more unsettling!	effective at achieving it. The evidence does not suggest that it is, unless the HbA1c is ≥ 8.0 and it is accompanied by education and feedback.
	27	Patients with diabetes need to monitor their blood sugar levels frequently throughout the day. SMBG is recognized as an important component of the treatment plan , it provides information pts need to assess how food, physical activity and medications affect their glucose levels. The information provides immediate feedback and data to enable persons with DM to make changes in their management plans on a daily basis. SMBG aids in improving patients’ recognition of hypoglycemia or severe hyperglycemia which in the long run would save thousands of dollars for a trip to ED or even a hospital admission.	See comment #20
	28	As stated in the article by Parkin and Davidson (2009): “Studies have clearly demonstrated the value of SMBG levels in the management of T1DM and insulin-treated T2DM. ^{2,41} Using the American Association of Clinical Endocrinologists (AACE) road map ⁴² with the help of SMBG, Lingvay and colleagues ⁴³ showed that in treatment-na metformin and insulin could achieve a normal HbA1c in a period of just 3 months. Other studies like the Treat-to-Target ⁴⁴ and 1-2-3 ⁴⁵ trials were able to achieve the targets by titration of insulin dose based on SMBG.”	This guidance recommends coverage of SMBG supplies in patients with T1DM or T2 DM on multiple daily injections.
	29	Parkin and Davidson (2009): “Large, randomized, controlled trials have clearly demonstrated a causal relationship between poor glycemic control and the development of microvascular disease. ^{2,3} The link between effective diabetes management and reduced macrovascular disease has also been established. ^{4,5} Studies by Gaede and colleagues showed that intensive management of all risk factors, including elevated lipids, blood pressure, and glycemia, had significant beneficial effects on cardiovascular-related deaths. ⁶ This intensive therapy was also found to be cost-effective.”	Parkin is a commentary on pattern analysis, not a study and not specific to T2DM.
	30	Parkin and Davidson (2009): “Self-monitoring of blood glucose (SMBG) is an important adjunct to HbA1c because it can distinguish among fasting, preprandial, and postprandial hyperglycemia; detect glycemic excursions; identify and assist in monitoring resolution of hypoglycemia; and provide immediate feedback to patients about the effects of food choices, activity, and medication on glycemic control. ³⁷ HbA1c testing cannot make these distinctions or provide this information. Thus, SMBG is recognized as an important tool that guides glycemic management strategies and has the potential to improve problem-solving and decision-making skills for both the person with diabetes and his or her health care professional.”	See comment #29
	31	In another article that is attached by Sarol and Nicodemus (2005), “ Multi-component diabetes management programs with self-monitoring of blood glucose result in better glycemic control among non-	This citation was published before the date of the Clar review. The HTAS bases their guidance documents on reviews of

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		insulin-using type 2 diabetes patients.”	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.
	32	Please reconsider your proposal to limit the ability of our diabetes patients to test their BS levels regardless of their A1C level. If you are suggesting that only those persons with diabetes who are already in poor control, facing terrible and costly complications be allowed to test BS levels only once a day, then I believe the cost to manage this deadly disease will only go higher. Not to mention, the cost of health care for those persons who currently have good control will worsen and cost more in the long run as well. SMBG is an integral component of controlling diabetes and is a valuable tool that persons with diabetes must have access to on a daily basis.	See comment #22
Internist, Endocrinologist, Associate Professor Portland, OR	33	I am a board-certified internist and board-certified endocrinologist. I have been seeing patients with diabetes since graduation from medical school in 1978. I have no financial ties with any company that manufactures or sells glucose monitoring equipment or strips.	Thank you for taking the time to comment.
	34	My objections to the suggested coverage: <ol style="list-style-type: none"> 1. The coverage suggests that only patients with an HbA1c of 8.0% would benefit from self-monitoring of blood glucose. It implies that there is no benefit in testing individuals with an HbA1c of less than 8.0%. I believe that glucose monitoring is useful irrespective of A1C level. 2. The specific coverage suggests that once weekly testing is adequate. I believe that once weekly testing is inadequate. 	The evidence does not suggest that SMBG results in clinically significant improvement in HbA1c, and there is no evidence of improvement in other patient important outcomes. SMBG appears to have the most effect in patients with HbA1c >8, and there was no difference between weekly and more frequent testing.
	35	Parts of the suggested coverage with which I agree: <ol style="list-style-type: none"> 1. It encourages utilization of structured education and feedback regarding testing presumably to facilitate meaningful testing in those who receive test strips. 	Thank you for your comment.
	36	Pertinent Information from the Literature:	See comment #12

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		<p>Two important studies highlight the importance of SMBG in type 2 patients. The Structured Testing Program (STeP) study evaluated the utility of structured testing and feedback with SMBG (Polonsky et al). Patients in the intervention group received training on how to test and how to identify and address problematic glycemic patterns. These patients were instructed to utilize a 7-point SMBG testing profile (fasting, preprandial, 2 hours postprandial and bedtime SMBG). In contrast, those in the usual care group were provided test strips but no additional instruction or feedback. <u>After 1 year, participants in the intervention group demonstrated an overall 0.3% reduction in HbA1c; an even greater reduction of 0.5% was notable among those who were identified as adherent.</u></p> <p>In the ROSES Study Group trial, participants in the intervention group were assigned a self-monitoring-based disease management strategy that centered on modification of lifestyle according to SMBG. <u>After 6 months, significantly greater reduction in HbA1c (0.5% reduction) was observed in the intervention group compared to usual care (Franciosi et al).</u> This study highlights the potential benefit of SMBG in impacting behavior and lifestyle modification.</p>	
	37	<p>My recommendations regarding the HERC coverage guidance for non-insulin dependent type 2 diabetes patients:</p> <ol style="list-style-type: none"> 1) Eliminate the restriction of testing once weekly and remove the cutoff HbA1c. 2) Continue the current Medicare Guidelines for 100 test strips provided over a 90 day period. If this is not possible, consider automatic coverage for 90 days to all patients every year with one refill regardless of HbA1c. 3) Consider allowing a greater number of strips for certain conditions: <ol style="list-style-type: none"> a. Newly diagnosed patients b. Patients changing treatment c. Patients with history of hypoglycemia d. Patients with multiple comorbid conditions or microvascular or macrovascular complications of diabetes e. Patients with gestational diabetes or diabetes in pregnancy <p>I thank the committee for their time and review of this topic. Thank you for asking for public comment.</p> <p>References:</p> <ol style="list-style-type: none"> (1) Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, non-insulin treated type 2 diabetes: results from the Structured Testing Program study. <i>Diabetes Care</i> 2011; 34(2):262-7. (2) Franciosi M, Lucisano G, Pellegrini F, Cantarello A, Consoli A, Cucco L, Ghidelli R, Sartore G, Sciangula L, Nicolucci A; ROSES Study Group. ROSES: role of self-monitoring of blood glucose and intensive 	<p>The studies cited to support these suggestions only used between 8 and 12 strips/ month. Unclear why over 30 strips/month are being requested.</p> <p>This document does not pertain to pregnant patients.</p> <p><i>For HTAS discussion</i></p>

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		education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial. Diabet. Med. 2011; 28(7):789-96.	
<i>Registered Nurse, Diabetes Educator The Dalles, OR</i>	38	I am a Registered Nurse and Certified Diabetes Educator. I work in the physician clinics as a diabetes educator. I have many concerns regarding the severe limitation of glucose strips being suggested. All Type 1 and many Type 2 diabetes patients take insulin and many times a day. Insulin dosing is still not an exact science and too much insulin can be life threatening. Low blood sugars have symptoms and without being able to test patients may choose to go to the emergency room because they fear for their life. Strips are cheaper. Patients also develop low blood sugar unawareness where they have no symptoms, can become unconscious, have seizures, and if they happen to be driving could hurt themselves and/or others. What if the person they injure in the other car has government insurance? Strips still cheaper. Reducing A1c's by 1% lowers the risk of long term complications by 30% and at 8% they are already above the recommended goal of < 7%. Also increased standard deviations increase long term complications and improvement in those is impossible without monitoring. Long term complications cost more money. Strips still cheaper. In my work I have also learned that people are motivated by looking at their blood sugars. They tend to do better taking care of their diabetes. Good diabetes self care costs less.	Thank you for taking the time to comment. The evidence does not support any benefit of SMBG in preventing hypoglycemia in T2DM, and has been shown to only reduce HbA1c by 0.5% or less, depending on whether it is accompanied by structured education and feedback and if the baseline HbA1c is ≥ 8.0, not 1%.
	39	Some ideas to control costs would be to keep medical supply companies from calling patients and selling them things they don't need. Buy glucose strips in bulk to keep the cost down. More than one brand is necessary depending on the patient's specific needs, such as vision impaired, insulin pump compatibility. Required that patients turn in a log indicating how often they test so they aren't allowing strips to outdate. Patients need to see a diabetes educator so they can learn how to use the blood glucose readings that they are doing. Monitoring is the most useful when the patient learns to react to the numbers. The patient needs to learn how a meal effects their blood sugar so they can make change or how a walk lowers blood sugar. We need to decrease long term complications to save money not decrease the ability for people with diabetes to do good self care.	Thank you for suggesting cost saving measures. Most of these are implementation issues that are beyond the scope of this guidance.
<i>LifeScan, Inc. Milpitas, CA</i>	40	LifeScan, Inc., a Johnson & Johnson Company, is respectfully submitting comments on the topic of Glucose Monitoring for the Oregon Health Evidence Review Commission (HERC) LifeScan, a leading manufacturer of blood glucose monitoring products and other diabetes management systems, is committed to improving the lives of all patients with diabetes today and with continued innovation in the future. We ask for your thoughtful consideration of the potential impact of restricting access to glucose monitoring products and supplies for individuals with diabetes in the State of Oregon. In doing so, we further request that the HERC consider following the standards of care established by the American Diabetes Association (ADA) and the American Association of Clinical Endocrinologists (AACE) for the care of patients with diabetes to ensure both quality and cost-effective patient care. 1, 2	Thank you for your comment.

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	41	Self-monitoring of blood glucose (SMBG) is an integral part of diabetes care management ^{1(A)} and has been shown to have both clinical ^{2 (B)} and economic benefits. ^{3(A)} SMBG helps patients with diabetes in four distinct ways: (1) SMBG allows patients and clinicians to detect high or low blood glucose levels, thereby facilitating therapeutic adjustments to achieve long-term HbA1c goals; (2) it helps protect patients by allowing them to immediately confirm acute hypoglycemia or hyperglycemia; (3) it facilitates patient education about diabetes and its management by giving patients more self-care responsibilities; and (4) it can help motivate people toward healthier behavior. ^{1 (B)}	Thank you for sharing the ADA and AACE recommendations. Specialty society guidelines have varying levels of adherence to evidence-based principles, and unless supported by specific evidence supporting the recommendations, are considered a lower level of evidence.								
	42	The optimal SMBG testing frequency can vary over time for any individual patient. For example, patients whose blood glucose is poorly controlled or has large variability may require more frequent testing to help bring blood glucose into better control. SMBG is also used to detect hypoglycemia. This is important for patients who take insulin or insulin secretagogues, and for patients with hypoglycemia unawareness. Additionally, it is recommended that patients suffering from hypoglycemic events retest to ensure their blood glucose levels have risen following treatment.	HTAS is aware of the clinical uses of SMBG.								
	43	<u>Type 2 Diabetes Mellitus Not Requiring Insulin</u> HERC recommends that, for patients with Type 2 diabetes mellitus not requiring insulin, home blood glucose monitors and related diabetic supplies be covered only for those with HbA1c levels greater than 8%. However, please note that, for adult patients with diabetes, the ADA ^{1(D)} recommends a HbA1C goal < 7%, and AACE ^{2 (A)} , and the International Diabetes Federations (IDF) ^{5 (A)} recommend a goal of ≤6.5% . Lowering HbA1C to 7% or less has been shown to reduce microvascular and neuropathic complications of diabetes ^{1 (c)} . Therefore, we request the HERC reconsider the proposed restrictions on SMBG, which may prevent patients from achieving an HbA1C of < 7.0%.	See comment #41. The evidence does not support the effectiveness of SMBG in this patient population (HbA1c<8.0)								
	44	<table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="background-color: #2c5e8c; color: white;"></th> <th style="background-color: #2c5e8c; color: white;">ADA 1(D) (non-pregnant adults with DM*)</th> <th style="background-color: #2c5e8c; color: white;">AACE2(a) (all patients with DM)</th> <th style="background-color: #2c5e8c; color: white;">IDF5 (A) (all patients, T2DM§)</th> </tr> </thead> <tbody> <tr> <td style="background-color: #d9e1f2;">HbA1c:</td> <td style="background-color: #d9e1f2;"><7.0%</td> <td style="background-color: #d9e1f2;">≤6.5%</td> <td style="background-color: #d9e1f2;">≤6.5%</td> </tr> </tbody> </table> <p>DM = diabetes mellitus; §T2DM = type 2 diabetes mellitus</p> <p>Guidelines from professional societies suggest that optimal SMBG frequency must be individualized in non-insulin treated type 2 diabetes mellitus patients. 1,2,5 The recommendation by HERC that the frequency of blood glucose testing for patients with Type 2 diabetes mellitus not requiring insulin be limited to once a week is not consistent with these guidelines.</p>		ADA 1(D) (non-pregnant adults with DM*)	AACE2(a) (all patients with DM)	IDF5 (A) (all patients, T2DM§)	HbA1c:	<7.0%	≤6.5%	≤6.5%	See comment #43.
	ADA 1(D) (non-pregnant adults with DM*)	AACE2(a) (all patients with DM)	IDF5 (A) (all patients, T2DM§)								
HbA1c:	<7.0%	≤6.5%	≤6.5%								
	45	We agree that structured education and feedback programs for SMBG is needed. However, feedback on actions to take based on blood glucose results would be very limited if testing only occurred once per week.	The Clar review found that more frequent testing did not result in improved HbA1c.								
	46	More frequent SMBG can result in improvements in HbA1c. Karter et al. showed that across four patient groups (type 1 DM, T2DM treated with insulin, T2DM treated with oral medications and T2DM treated with	Both citations were published before the date of the Clar review (2001 and 2006).								

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		<p>diet), SMBG adherence was significantly associated with improved glycemic control, and that increased frequency of SMBG was related to decreased HbA1C levels.^{6(A)} A second study showed that among new users, as SMBG testing frequency increased, there was an associated graded decrease in HbA1C (relative to nonusers) regardless of diabetes therapy (diet and exercise vs. orals vs. insulin therapy) ($p < 0.0001$). Changes in SMBG frequency among prevalent users were also associated with an inverse graded change in HbA1C among patients taking oral agents and insulin groups ($p < 0.0001$).⁷</p>	<p>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.</p>
	47	<p>The studies cited in the meta-analysis referenced by HERC did not provide either information on outcomes by treatment received or insights to allow the authors to determine which patients may benefit most and which least from SMBG. Many of the studies that fail to show an SMBG benefit have limitations, including lack of statistical power, inconsistencies in recommended monitoring frequencies, lack of a control arm, and failure to stratify by type of treatment. Importantly, and inconsistent with the recommendations of HERC, other limitations of these studies include treating SMBG as a direct intervention rather than a tool linked to appropriate education and behavior/therapy changes; of standardization of training and advice given on modification of therapy; and lack of education to accompany the self-monitoring intervention.^{6, 8(B)}</p>	<p>While the Clar review identifies the limitations of the evidence base and does include a number of observational studies, it also includes 26 RCTs, and remains the best information available on which to base conclusions and policy recommendations.</p>
	48	<p><u>Type 1 Diabetes and Type 2 Diabetes on Insulin Therapy</u></p> <p>The ADA Guidelines recommend that SMBG be carried out three or more times daily for patients using multiple daily insulin injections or insulin pump therapy.^{1 (A)} The AACE recommends that SMBG should be performed by all patients using insulin (<u>minimum</u> of twice daily and ideally at least before any injection of insulin).^{2(B)} We agree that the frequency of testing for all insulin using diabetes patients should be individualized, with these recommendations in mind.</p> <p>Thank you for the opportunity to provide commentary regarding 2012 Draft Coverage Guidance: Self-monitoring of Blood Glucose for Type 1 & Type 2 Diabetes. We hope you have found the information and suggestions offered in this letter helpful. Thank you in advance for your consideration of our recommendations.</p> <p>References</p> <p>1 American Diabetes Association. "Standards of medical care in Diabetes - 2011." <i>Diabetes Care</i> 34, no.</p>	<p>Thank you for your comment.</p>

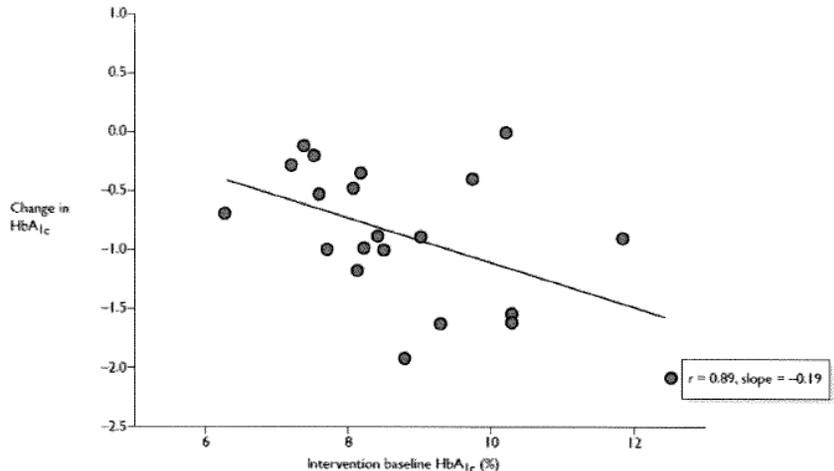
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		<p>Supplement 1 (January 2011): S11 - S61.</p> <p>2 AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. "American Association of Clinical Endocrinologists Medical Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan." <i>Endocrine Practice</i> 17 Supplement 2 (2011): 1-52.</p> <p>3 Klonoff, DC. Benefits and Limitations of Self-Monitoring of Blood Glucose. <i>J Diabetes Sci Technol</i> 2</p> <p>4 Tunis, SL and ME Minshall. "Self-monitoring of blood glucose in type 2 diabetes: cost-effectiveness in the United States." <i>The American Journal of Managed Care</i> 14, no. 3 (March 2008): 131-140.</p> <p>5 International Diabetes Federation Guidelines Task Force. <i>Global Guidelines for Type 2 Diabetes</i>. Brussels: International Diabetes Federation, 2005.</p> <p>6 Karter, AJ, LM Ackerson, JA Darbinian, RB D'Agostino Jr, A Ferrara, J Liu and JV Selby. "Self-monitoring of blood glucose levels and glycemic control: The Northern California Kaiser Permanente Diabetes Registry." <i>The American Journal of Medicine</i> 111 (July 2001): 1-9.</p> <p>7 Karter AJ et al. Longitudinal Study of New and Prevalent Use of Self-Monitoring of Blood Glucose. <i>Diabetes Care</i> 2006; 29:1757-1763.</p> <p>8. Clar et al. Self-monitoring of blood glucose in type 2 diabetes: systematic review. <i>Health Technology Assessment</i> 2010: 14:</p>	
<p><i>Roche Diagnostics</i> Indianapolis, Indiana</p>	49	<p>On behalf of Roche Diagnostics, we welcome the opportunity to comment on the draft guidance. Our comments focus on HERC's recommendation for Type 2 diabetes mellitus (T2DM) patients:</p> <ul style="list-style-type: none"> • The proposed limit of once-a-week testing for T2DM patients not requiring insulin unduly restricts physician discretion to order medically necessary testing. • The proposed testing limits are not supported by clinical evidence or practice. • Limiting coverage to T2DM patients with HbA1c levels >8.0% is not supported by clinical evidence or practice. <p>We recommend that testing for T2DM patients not requiring insulin is covered up to once per day, on average, and not be limited to those with HbA1c >8.0%.</p>	Thank you for taking the time to comment. HTAS disagrees that the proposed limits are not supported by clinical evidence.
	50	<p>I. Proposed Limits Unduly Restrict Physician Discretion to Order Medically Necessary Testing</p> <p>We agree that diabetes testing supplies should be used only when medically necessary, but are concerned the limits unduly restrict physician discretion to order medically necessary testing. Clinical guidelines provide testing frequency should be individualized. The ADA guidelines state: "The frequency and timing of SMBG should be dictated by the particular needs and goals of the patient."¹ Similar statements are found in other guidelines.^{2,3,4,5}</p>	Physicians are free to order whatever testing they feel is medically necessary. This document addresses recommendations on coverage. The patient can of course purchase additional strips on their own.
	51	<p>Patients using oral agents may test more frequently than once-weekly due to hypoglycemic episodes, changes medications/diet/activity levels, intercurrent illness, glucose control not at target, and new or worsening symptoms of hyperglycemia.</p>	HTAS is aware of this.
	52	<p>Because of the high prevalence of diabetes (~225,000 in Oregon⁶), if even a small percentage of patients</p>	There is no evidence that testing once

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		appropriately test at rates > one-per-week, a substantial number of beneficiaries would either be required to go through appeals, or would test less than optimally. ⁷ This puts an unnecessary burden on beneficiaries and providers, and would likely result in reduced self-monitoring and poorer patient outcomes.	weekly or less results in poorer patient outcomes. The ONLY evidence of benefit pertains to HbA1c, an intermediate outcome, while there is some evidence of harm with regard to possible increased depression.
	53	<p>II. Testing Limits Are Not Supported by Clinical Evidence or Practice</p> <p>Clinical evidence suggests increased testing frequency improves clinical outcomes:</p> <p>1. Karter (2006) – In a longitudinal analysis, the authors conclude: “[I]n those receiving pharmacologic therapy; decreases in SMBG frequency were significantly associated with a modest worsening in glycemic control, whereas increases in SMBG were associated with modest improvements in control.”⁸</p>	See comment #31
	54	<p>2. Karter (2001) – In a cohort study to assess the relationship between self-monitoring and HbA1c, the authors conclude: “More frequent self-monitoring of blood glucose levels was associated with clinically and statistically better glycemic control regardless of diabetes type or therapy.”⁹</p>	See comment #31
	55	The draft guidance is based on a systematic review reporting that frequent testing (3-7 times/week) compared to less frequent testing (1X/week or as usual) resulted in a mean difference in HbA1c of 0.20 (0.01 to 0.41) (result not significant). ¹⁰ This conclusion is based on two studies. The first study investigated whether once-weekly measurement is non-inferior to more frequent testing on metabolic control, hypoglycemia and/or hyperglycemia, or adverse events. ¹¹ The authors concluded that low frequency testing is non-inferior. However, non-inferiority does not rule out portions of the population that benefit from more frequent testing. Furthermore, the study excluded patients with ≥2 episodes of hypoglycemia requiring external support within three months, and patients with ≥1 severe metabolic events within three months-patients who could benefit from more frequent testing.	Scherbaum 2008. Commenter appears to be suggesting that increased testing will lead to less hypoglycemia; however, the evidence does not support this.
	56	The second study investigated whether free strips improves glycemic control in T2DM patients. ¹² The intervention group tested 4.1 times/week whereas the control group tested 2.5 times/week. The authors conclude that free strips did not improve glycemic control. However, as average testing frequency was 3.5 times/week in the control group and 4.1 times/week in the intervention group, this study in no way supports a once-a-week testing limit.	Johnson 2006. Description of study is correct.
	57	These studies suggest the evidence on appropriate testing frequency is unclear. This is not surprising, as patients have different needs for testing and frequency should be individualized. Given this evidence, it is unclear how one could conclude that support for once/week testing is strong. ¹³	The strong recommendation incorporates balance between desirable/undesirable effects, quality of evidence, costs and values. Given that the only evidence of effectiveness pertains to an intermediate outcome (HbA1c), that there may be harms, and that cost is moderate, the

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			HTAS believes that a strong recommendation is warranted. <i>For HTAS discussion – consider changing recommendation to weak?</i>
	58	<p>III. Limiting Coverage to T2DM Patients With HbA1c Levels >8.0% Is Not Supported By Clinical Evidence or Practice</p> <p>The selection of HbA1c Levels >8.0% as the cut-off seems to be supported by the following statement: “Patients using diet alone or oral agents and having a higher baseline HbA1c (≥8.0%) may achieve greater reductions in HbA1c with SMBG compared to those with a lower baseline HbA1c (<8.0%). For patients with a baseline HbA1c >10%, SMBG may decrease HbA1c by a mean of -1.23% (95% CI, -2.31% to -0.14%) compared to no SMBG; for those with a baseline HbA1c 8% to 10%, SMBG may decrease HbA1c by a mean of -0.27% (95% CI, -0.40% to -0.14%); and those with baseline HbA1c < 8% may decrease HbA1c by a mean of -0.15% (95% CI, -0.33% to 0.03%). The reduction in HbA1c for patients with a baseline HbA1c < 8% is not statistically significant or clinically important.”</p>	Because Clar was unable to conduct a quantitative subgroup analysis (see below), this information was derived from Poolsup 2009, another good quality SR that was cited in the MED report. [Poolsup, N., Suksomboon, N., & Rattanasookchit, S. (2009). Meta-analysis of the benefits of self-monitoring of blood glucose on glycemic control in type 2 diabetes patients: an update. <i>Diabetes Technology & Therapeutics</i> , 11(12), 775-784. doi: 10.1089/dia.2009.0091]
	59	<p>This finding is not found in the Clar review. The review includes the following: Figure 1. Change from baseline as a function of baseline HbA1c (intervention groups)¹⁴</p>  <p>These data indicate that HbA1c levels decrease with testing from baseline values below and above 8.0%; there is no inflection point in the curve at HbA1c=8.0%. Furthermore, patients with HbA1c levels, 8.0% who</p>	Clar did not find adequate data on relevant subgroups in the original RCTs for quantitative subgroup analysis. As a crude method of determining if baseline HbA1c has an effect on the impact of SMBG, they plotted the change in HbA1c (over the course of the study) as a function of mean baseline HbA1c for the control and intervention groups in all 26 RCTs. This graph is for the intervention group. A very similar graph is also presented in Clar for the control groups, which also shows a moderate correlation. The translation is that the higher the HbA1c, the more likely it is that it will improve, either with or without SMBG. Each dot on this graph represents one study, unclear what commenter means by no inflection point at HbA1c = 8%.

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		would not be eligible for coverage under the draft guidance may achieve such HbA1c levels due to regular testing. If coverage for these patients is restricted, these patients may experience increases in HbA1c levels. Insofar as the target HbA1c in T2DM patients is <7.0%, these data indicate that it is clinically meaningful to continue to test in this population. ¹⁵	
	60	In summary, we recommend that testing for T2DM patients not requiring insulin is covered up to once per day, on average, and not be limited to those with HbA1c >8.0%.	<i>For HTAS discussion</i>
Registered Dietitian, Diabetes Educator Newport, OR	61	In response to the proposal of reduced SMBG in type II diabetes: I STRONGLY disagree in this new proposal that testing strips should only be offered to patients with an A1C of higher than 8%. This would be a huge DISINCENTIVE for patients to self-manage their diabetes. The cornerstone of diabetes care in this country is physician referral to an outpatient diabetes education program. In these programs, patients are given SELF-EFFICACY and CONFIDENCE in which to manage their diabetes. This makes them feel empowered. By proposing a reduced amount of test supplies, you are, in fact, TAKING AWAY THEIR SELF-EFFICACY . This will be extremely discouraging to patients, as they will then need to rely on A1C (which many times isn't tested every 3-6 months as recommended).	Thank you for taking the time to comment. If there is an effect of SMBG on patient self-efficacy, it is not translated into a significant effect on HbA1c (unless baseline level is ≥ 8.0) or other patient important outcome.
	62	Please consider this testimony coming from a diabetes educator, who KNOWS what motivates these patients. Possibly the strongest factor of motivation is getting these "instant" results of SMBG. They don't have to wait 3-6 (or sometimes 12) months for a doctor to tell them they're doing a good (or bad) job. They can monitor their own disease process, and phone the doctor if they have concerns. I am very concerned for the state of people with diabetes if this ESSENTIAL tool is taken away from them. I urge you to reconsider this dangerous, destructive choice.	See comment #61
Bayer HealthCare Wayne, NJ	63	Bayer HealthCare LLC ("Bayer") appreciates the opportunity to offer recommendations to the Health Technology Assessment Subcommittee of the Oregon Health Evidence Review Commission (HERC) on its draft guidelines for non-insulin using Type 2 patients with diabetes. Bayer remains committed to providing diabetes patients with innovative diabetes testing products and services needed to better manage their disease and live healthier lives. We offer the analysis and recommendations below for the Commission's consideration regarding proposed coverage changes for non-insulin using Type 2 patients with diabetes. We recommend the Commission maintain coverage for all patients with diabetes and allow health care professionals to determine the appropriate testing frequency based on their clinical judgment.	Thank you for taking the time to comment. The evidence does not support the efficacy of SMBG in T2DM except when baseline HbA1c is ≥ 8.0 when it is accompanied by education and feedback. Unlimited coverage would be fiscally irresponsible.
	64	Incidence of Diabetes Estimates project 1 in 3 US adults will have diabetes by 2050. ¹ As diabetes is the leading cause of blindness, kidney failure and amputations of feet and legs unrelated to accidents or injury, the toll of improper control among those with diabetes cannot be overstated. Data from the US Centers for Disease Control and Prevention illustrate the concern for Oregon, with the percentage of Oregon adults with diabetes almost doubling from 3.4% in 1994 to 7.7% in 2010 (see below).	HTAS is aware of the demographics of DM.

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	65	<p>In light of these statistics, we urge the Authority to consider the importance of glucose control in managing the progression of diabetes and its related medical complications and costs. Unintended consequences may result from reducing patient access to diabetes testing supplies used to manage patients’ diabetes. Such restrictions may adversely impact patient care and increase medical costs associated with complications resulting in potential emergency department visits and hospitalizations.</p> <p>Oregon - Percentage of Adults (aged 18 years or older) with Diagnosed Diabetes, 1994 – 2010²</p> <table border="1"> <caption>Oregon - Percentage of Adults (aged 18 years or older) with Diagnosed Diabetes, 1994 – 2010²</caption> <thead> <tr> <th>Year</th> <th>Crude ** (%)</th> <th>Age-Adjusted † (%)</th> </tr> </thead> <tbody> <tr><td>1994</td><td>4.0</td><td>3.8</td></tr> <tr><td>1995</td><td>4.2</td><td>4.0</td></tr> <tr><td>1996</td><td>4.5</td><td>4.2</td></tr> <tr><td>1997</td><td>4.8</td><td>4.5</td></tr> <tr><td>1998</td><td>5.0</td><td>4.8</td></tr> <tr><td>1999</td><td>5.2</td><td>5.0</td></tr> <tr><td>2000</td><td>5.5</td><td>5.2</td></tr> <tr><td>2001</td><td>5.8</td><td>5.5</td></tr> <tr><td>2002</td><td>6.0</td><td>5.8</td></tr> <tr><td>2003</td><td>6.2</td><td>6.0</td></tr> <tr><td>2004</td><td>6.3</td><td>6.1</td></tr> <tr><td>2005</td><td>6.4</td><td>6.2</td></tr> <tr><td>2006</td><td>6.5</td><td>6.3</td></tr> <tr><td>2007</td><td>6.6</td><td>6.4</td></tr> <tr><td>2008</td><td>6.8</td><td>6.6</td></tr> <tr><td>2009</td><td>7.0</td><td>6.8</td></tr> <tr><td>2010</td><td>7.8</td><td>7.2</td></tr> </tbody> </table>	Year	Crude ** (%)	Age-Adjusted † (%)	1994	4.0	3.8	1995	4.2	4.0	1996	4.5	4.2	1997	4.8	4.5	1998	5.0	4.8	1999	5.2	5.0	2000	5.5	5.2	2001	5.8	5.5	2002	6.0	5.8	2003	6.2	6.0	2004	6.3	6.1	2005	6.4	6.2	2006	6.5	6.3	2007	6.6	6.4	2008	6.8	6.6	2009	7.0	6.8	2010	7.8	7.2	The Clar review concluded that SMBG in T2DM is not cost-effective.
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	66	<p>Test Frequency Should be Determined by the Treating Health Care Provider</p> <p>For successful glucose control, patients should perform SMBG in a manner that supports their diabetes control and better informs their clinicians. This requires an individualized approach to treatment targets, and the timing, and frequency of SMBG.³</p>	See comment #63																																																						
	67	<p>The <i>Roses</i> randomized clinical trial estimated the efficacy of self-monitoring-based management strategies in patients with Type 2 diabetes treated with oral agent monotherapy.⁴ Study participants utilized SMBG 3 times per week on average. Patients were randomly allocated to either a self-monitoring-based disease management strategy or usual care (ratio 3:1) and followed up for 6 months. Education centered lifestyle modification according to self-monitoring readings. The primary endpoint was mean change in HbA1c levels, with an absolute mean difference between the intervention and control groups of -0.5%. The study concluded that self-monitoring disease management strategies, primarily led by diabetes nurses and allowing timely and efficient use of self-monitoring readings, can improve metabolic control via lifestyle modification and weight loss.</p>	See comment #12																																																						
	68	<p>Similarly, the <i>STeP</i> randomized clinical trial assessing structured blood glucose testing effectiveness found that appropriate use of structured SMBG significantly improves glycemic control and facilitates more timely/aggressive treatment changes in non-insulin treated Type 2 diabetes.⁵ Focusing on poorly</p>	See comment #12																																																						

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		controlled, non-insulin patients with Type 2 diabetes, study participants utilized SMBG twice per week on average.	
	69	No valid clinical support for the Commission’s proposal exists to limit SMBG coverage for non-insulin using Type 2 patients to one test per week. The Oregon Health and Science University document cited in the draft guidance does not appear to be published in any medical treatise. There is no indication that this document has been peer-reviewed or endorsed by any diabetes professional societies. We strongly urge the release of these data to assure patients, clinicians and other stakeholders can better assess and comment on the study objectives, research design, results and conclusions which will have a significant impact on patient care.	The MED report is a proprietary product; however, it is a summary of the published, peer reviewed literature on this topic. The primary evidence source for the MED report was the Clar 2011 review, and all references for the MED report are published and have been peer reviewed. The full reference list for the MED report is available on the HERC website. Professional society endorsement is not a goal of the HTAS.
	70	The Commission’s reliance in its draft guidance upon the systematic review entitled: <i>Self-Monitoring of Blood Glucose in Type 2 Diabetes</i> is also a concern. This systematic review was based upon poorly designed clinical trials. Indeed, the systematic review article concedes that the “review identified 30 RCTs, although few were of high quality.” In some trials included in this systematic review, patient participants were not instructed on how to interpret the meaning of SMBG results and, therefore did not use SMBG data. ⁶ Further, in other included trials, participating health care providers did not incorporate SMBG data into their therapeutic treatment decisions. ⁷	HTAS concurs with this statement. This is, however, the best evidence available, and the commenter has not provided other evidence supporting their position.
	71	A “point-counterpoint” also took issue with the Cochran SMBG meta-analysis, citing a lack of consideration of how the “SMBG ‘tool’ was defined in the protocol of each study reviewed and how the resulting SMBG data were used clinically.” ⁸ Specifically, five main problems were cited in the discussion: 1. The recommended timing and frequency across the studies reviewed were variable, often random, and ultimately not adequate. In rare cases were they sufficient to secure reliable findings for clinical decision making. 2. It was unclear if <i>patients</i> were knowledgeable about SMBG and had the necessary skills to use the SMBG data in the studies reviewed. 3. It was unclear if <i>clinicians</i> in the studies reviewed were knowledgeable about SMBG and had the necessary skills to use the SMBG data 4. It was unclear if SMBG data was collected and recorded in a manner that permits blood glucose patterns to be readily observable and easily intelligible for clinicians and patients. 5. In addition, the Cochrane review left out studies that were well-designed and demonstrated positive outcomes for SMBG use among patients with type 2 diabetes not on insulin.	The HTAS does not disagree with the limitations of the evidence, but again, commenter has not provided credible evidence to dispute the findings, nor have they identified what studies they believe were erroneously omitted from Clar.
	72	Based upon the foregoing, the Commission’s proposal to limit SMBG testing in non-insulin using Type 2	Neither of these studies address the value

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		diabetes patients is unsupported by the references cited in its draft guidance and is clearly refuted by the <i>Roses</i> and <i>STeP</i> randomized clinical trials discussed above. For these reasons, we recommend that the Commission withdraw this proposal and continue to allow treating health care providers to use their clinical judgment in determining the SMBG test frequency for non-insulin Type 2 diabetes patients.	of SMBG over no SMBG. See comment #12.
	73	Any HbA1c Targets Should be Consistent With Professional Guidelines Professional guidelines support the use of HbA1c targets to access glycemic control. ⁹ The purpose of establishing glycemic targets is to foster improved glycemic control and initiate earlier interventions to reduce the risk of costly diabetes-related complications. Contrary to the Commission’s proposed HbA1c target of >8%, professional guidelines recommend a lower threshold. The American Diabetes Association recommends HbA1c of <7%, while the American Association of Clinical Endocrinologists and the International Diabetes Federation recommend HbA1c targets of ≤6.5%.	HTAS is not proposing a HbA1c target. This coverage guidance is not a clinical guideline; it is a recommendation for coverage.
	74	We recommend that the Commission withdraw this proposal to limit coverage for non-insulin patients with Type 2 diabetes using an HbA1c target of >8% because this target is not supported by the professional guidelines outlined above.	Specialty society guidelines have varying levels of adherence to evidence-based principles, and unless supported by specific evidence supporting the recommendations, are considered a lower level of evidence. The Clar review does not support the efficacy of SMBG in patients with HbA1c <8.
	75	In conclusion, clinical evidence supports the value of SMBG for all patients with diabetes. Bayer respectfully requests that the Commission withdraw its proposal to limit coverage for non-insulin using Type 2 patients and maintain its existing coverage criteria. References: 1 Centers for Disease Control and Prevention. Diabetes: Successes and opportunities for population-based prevention and control: At a glance 2011. Accessed June 19, 2012 at: http://www.cdc.gov/chronicdisease/resources/publications/AAG/ddt.htm . 2 Center for Disease Control and Prevention. Oregon - Percentage of Adults (aged 18 years or older) with Diagnosed Diabetes, 1994 – 2010. Access June 21, 2012 at: http://apps.nccd.cdc.gov/ddtstrs/Index.aspx?stateId=41&state=Oregon&cat=prevalence&Data=data&view=TO&trend=prevalence&id=1 3 Klonoff DC, et al. Consensus Report: The current role of self-monitoring of blood glucose in non-insulin-treated Type 2 diabetes. <i>J Diabetes Sci Technol</i> . 2011;5(6):1529-1548. 4 Franciosi M, Pellegrini F, De Berardis G, et al. The QuED Study Group: self-monitoring of blood glucose in non-insulin-treated diabetic patients: a longitudinal evaluation of its impact on metabolic control. <i>Diabet Med</i> . 2005;22:900 –906, 2005.	HTAS disagrees that the evidence supports the value of SMBG.

HERC Coverage Guidance – Self-monitoring of Blood Glucose Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		<p>5 Polonsky WH, Fisher L, Schikman CH, Hinnen DA, Parkin CG, Jelsovsky Z, Petersen B, Schweitzer M, Wagner RS. Structured self-monitoring of blood glucose significantly reduces A1c levels in poorly controlled, noninsulin-treated Type 2 diabetes: results from the Structured Testing Program study. <i>Diabetes Care</i>. 2011;34(2):262-267.</p> <p>6 Klonoff DC, Blonde L, Cembrowski G, et al. Consensus Report: The Current Role of Self-Monitoring of Blood Glucose in Non-Insulin-Treated Type 2 Diabetes. <i>J Diabetes Sci Technol</i>. 2011: 5(6):1529-1548.</p> <p>7 Ibid Klonoff DC, et al. <i>J Diabetes Sci Technol</i>. 2011: 5:1529-1548.</p> <p>8 Polonsky WH, Fisher L. Self-monitoring of blood glucose in noninsulin-using type 2 diabetic patients. <i>Diabetes Care</i>. 2013;36:179-182.</p> <p>9 American Diabetes Association. <i>Diabetes Care</i>. 2011;34(Suppl 1):S11-S61. Handelsman Y, et al. <i>Endocr Pract</i>. 2011;17(Suppl 2):1-52. International Diabetes Foundation. Guideline for management of postmeal glucose. Accessed March 15, 2012 at: http://www.idf.org/webdata/docs/Guideline_PMG_final.pdf.</p>	

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