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

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| Farahnaz Joarder, MD<br>Assistant Professor, Endocrinology & Diabetes, Oregon Health & Science University | 1 | Statement in reply to HERC Coverage Guidance:<br>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.<br>1. It suggests that only patients with an HbA1c of 8.0% would benefit from self-monitoring of blood glucose.<br>2. It also, conversely suggests that there is no clinical benefit in testing individuals with an HbA1c of less than 8.0%.<br>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.<br>4. It encourages utilization of structured education and feedback regarding testing presumably to facilitate meaningful testing in those who qualify to receive test strips.<br>5. The number of individuals impacted by this is significant given the prevalence of type 2 diabetes.<br>6. There is potential influence on the policy/coverage for individuals currently covered by other government programs and commercial insurance.<br>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).<br>a. The AADE 7 are as follows:<br>i. Skills and knowledge acquisition in key self-care areas of healthy eating | 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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| | | ii. Physical activity<br>**iii. Glucose monitoring**<br>iv. Medication management<br>v. Reduce risks of acute and chronic complications<br>vi. Problem solving of diabetes care related issues<br>vii. Psychosocial adaptation to living with diabetes | |
| | 5 | 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. | Many of the trials that were included in the Clar review were fair to good quality (total of 11 of the RCTs). |
| | 6 | One of the major references sited 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. | Thank you for this summary of the Clar review. |
| | 7 | The authors very thoughtfully laid out the following important measures of consideration to help identify the utility of SMBG:<br>1) Did patients receive education about SMBG?<br>a. on how to test<br>b. on how to interpret the results<br>2) How were the results used?<br>a. For behavior change<br>b. Treatment adjustment by the patient<br>c. Treatment adjustment by the provider<br>3) What message did the patient receive from the provider?<br>a. Positive - to assist the patient in gaining control of their treatment<br>b. Negative - cause guilt associated with off range values<br>c. Did the patients get the impression that SMBG was good?<br>How does benefit vary by starting HbA1c, frequency, education, susceptibility to hypoglycemia, treatment, age, | See comment #6 |



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| | | time point during course of treatment of disease? | |
| | 8 | 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. | 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. |
| | 9 | 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. | HTAS agrees with this comment. |
| | 10 | 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 and the meaningful utilization of SMBG by the patient and the provider. | 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. |
| | 11 | In 2012 another comprehensive review on self-monitoring of blood glucose on non-insulin treated type 2 diabetes | This is also a Cochrane review that |

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| | | 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. | 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).<br>HTAS elected to provide broader coverage of SMBG supplies, including to patients who are newly diagnosed. |
| | 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 included. |
| | 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 | This trial WAS included. |

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| | | control group (8). | |
| | 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:<br>"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)"<br>AND<br>To achieve postprandial glucose |

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| | | | targets, postprandial SMBG may be appropriate. (E)<br>(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.<br><br>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 | See comment #19 |

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| | | provide education, structure and feedback on SMBG, that the provider in turn be allowed the choice to determine the specific testing frequency and duration of testing that is appropriate for a given patient. | |
| | 22 | With regard to the HERC coverage guidance for non-insulin dependent type 2 diabetes patients I suggest the following be considered:<br>1) Elimination of the restriction of testing once weekly and removal of a cutoff HbA1c<br>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.<br>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:<br>a. Patients newly diagnosed<br>b. Patients changing treatment<br>c. Patients on insulin secretagogues<br>d. Patients with history of hypoglycemia<br>e. Elderly patients<br>f. Patients with multiple comorbid conditions or microvascular or macrovascular complications of diabetes<br>**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 | I thank the committee for their time and review of this topic. I appreciate the opportunity to provide my perspective.<br>References:<br>(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, Endocr Pract. 2009; 15(6):540-59<br>(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. Health Technol Assess. 2010; 14(12):1-140.<br>(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 | Thank you for your input. |

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