

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### COVERAGE GUIDANCE: SELF-MONITORING OF BLOOD GLUCOSE FOR TYPE 1 & TYPE 2 DIABETES

Approved by HERC 12/5/2013; reaffirmed 1/14/2016

As a part of the coverage guidance monitoring process, the HERC decided on 1/14/2016 (see Appendix D) to reaffirm the existing coverage guidance and reconsider the need to update the topic during the regular two-year review cycle.

#### HERC COVERAGE GUIDANCE

For patients with type 1 diabetes and those with type 2 diabetes using multiple daily insulin injections, home blood glucose monitors and related diabetic supplies are recommended for coverage (*strong recommendation*).

For patients with type 2 diabetes not requiring multiple daily insulin injections, fifty test strips and related supplies are recommended for coverage at the time of diagnosis (*weak recommendation*). For those who require diabetic medication that may result in hypoglycemia, up to 50 test strips per 90 days are recommended for coverage (*weak recommendation*). If there is an acute change in glycemic control or active diabetic medication adjustment, an additional 50 strips are recommended for coverage (*weak recommendation*).

For all diabetic patients who are prescribed diabetic test strips, a structured education and feedback program for self-monitoring of blood glucose is recommended for coverage (*strong recommendation*).

*Note: This guidance does not apply to pregnant women.*

Note: Definitions for strength of recommendation are provided in Appendix A GRADE Element Description

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

Gerrity, M., Kriz, H., & Little, A. (2010). *Self-monitoring of blood glucose for type 1 and type 2 diabetes*. Portland, OR: Center for Evidence-based Policy, Oregon Health and Science University.

### *Key Sources Cited In MED Report*

Clar, C., Barnard, K., Cummins, E., Royle, P., & Waugh, N. (2010). Self-monitoring of blood glucose in type 2 diabetes: Systematic review. *Health Technology Assessment*, 14(12), 1-140. doi: 10.3310/hta14120

The Diabetes Control and Complications Trial Research Group. (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *New England Journal of Medicine*, 329(14), 977-986. doi: 10.1056/NEJM199309303291401

The summary of evidence in this document is derived directly from these evidence sources, and portions may be extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Diabetes mellitus (DM) is a serious chronic disease with significant morbidity, mortality, and cost. According to the Centers for Disease Control and Prevention, over 23 million (7.6% of the population) Americans have diagnosed (17.9 million) or undiagnosed (5.7 million) DM. Of the 17.9 million people with diagnosed diabetes, 2.2 million (14.5%) use insulin only, 10.3 million (57.6%) use oral medications only, 2.6 million (14.5%) use both, and 2.8 million (15.6%) do not take diabetes medications. An estimated \$174 billion in health care costs are either directly or indirectly related to DM, and 16% of total Medicaid expenses are for individuals with DM. Supplies for self-monitoring of blood glucose (SMBG) are an important portion of this expense. Self-monitoring of blood glucose is used to guide the day-to-day management of blood glucose through appropriate changes in diet, exercise, and/or medications to improve overall glycemic

control and clinical outcomes. However, there is controversy about the benefits and frequency of SMBG particularly for diabetics who do not use insulin.

## **Evidence Review**

### **Diabetes Requiring Multiple Daily Insulin Injections**

No studies address the frequency of SMBG for Type 1 diabetes except as a component of an intensive program to improve glycemic control. Recommendations for frequent (two to four times per day) and individualized SMBG in patients with Type 1 diabetes are based on the Diabetes Control and Complications Trial (DCCT), clinical expertise, and the practical issues associated with adjusting insulin dosing. Similar issues apply to Type 2 diabetes requiring multiple daily insulin injections (MDII).

### **Type 2 Diabetes**

A good quality systematic review (Clar 2010) published in 2010 included 26 RCTs that varied in quality (15 poor, 7 fair, and 4 good quality). They included patients with Type 2 diabetes on any oral treatment or combination of regimens, including lifestyle, oral agents or once-daily basal insulin. Most of the RCTs had more than 100 participants, but varied between 30 to over 800. The duration of the studies ranged from 12 weeks to 30 months, and participants were generally 50 to 65 years old. Fewer than half of the studies found that SMBG interventions improved HbA1c compared to the control, and all of these studies included an education and/or feedback component. The authors performed four separate meta-analyses, and report the following results:

- No study addressed the impact of SMBG on clinical outcomes (e.g., myocardial infarction, retinopathy). The main outcome evaluated was HbA1c, a surrogate outcome.
- SMBG decreases HbA1c by a mean of -0.21% (95% confidence interval [CI], -0.31% to -0.10%). A clinically important change in HbA1c has been defined as 0.5% or greater. Thus, a decrease in HbA1c of -0.21% may not be clinically important. Many of the interventions did not describe the educational component done in conjunction with SMBG.
- Structured education and feedback aimed at improving glycemic control may be necessary to achieve reductions in HbA1c through SMBG. Although not statistically significant, SMBG in conjunction with structured education and feedback (enhanced SMBG) decreased HbA1c by a mean of -0.20% (95% CI, -0.44% to 0.03%) compared to SMBG alone. Enhanced SMBG compared to no SMBG decreased HbA1c by a mean of -0.52% (95% CI, -0.98% to -0.06%). This decrease is clinically as well as statistically significant.

- One meta-analysis performed by Clar compared frequency of testing. The results of this analysis found 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%) favoring the *less* frequent testing group, although the result was not statistically significant.
- The 26 RCTs did not provide enough subgroup data to assess the impact of SMBG on patient subgroups, except for baseline HbA1c.
- Patients using diet alone or oral agents and having a higher baseline HbA1c ( $\geq 8\%$ ) may achieve greater reductions in HbA1c with SMBG compared to those with a lower baseline HbA1c ( $< 8\%$ ). 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.
- Few studies reported data on harms of SMBG. Six RCTs suggested the frequency of mild to moderate hypoglycemia may be increased with frequent SMBG, but results were inconsistent. One good quality cost-utility study found quality of life decreased slightly with intensive SMBG compared to standard care. Thirteen RCTs reported on weight and/or BMI and found no effect from SMBG. Two studies found an increase in depression with SMBG while two studies did not.

Two good quality cost-effectiveness studies found that SMBG was not cost effective compared to standard care. In one study, SMBG (about nine times per week) compared to no SMBG had an incremental cost per life-year gained was approximately US\$92,301 and cost per quality adjusted life-year gained was US\$107,331 (or approximately \$1 million dollars over ten years).

### **Evidence Summary**

Although no studies address the frequency of SMBG for Type 1 diabetes or Type 2 diabetes requiring MDII, frequent and individualized SMBG is recommended based on the practical issues associated with adjusting insulin dosing. For Type 2 diabetes not requiring MDII, no study addressed the impact of SMBG on clinical outcomes. Overall, SMBG decreases HbA1c by a mean of  $-0.21\%$ , although this is likely not clinically important. With regard to frequency of testing, there was no significant difference in HbA1c when comparing a frequency of three to seven times per week to one time per week. Patients using diet alone or oral agents and having a higher baseline HbA1c ( $\geq$

8%) may achieve greater reductions in HbA1c with SMBG compared to those with a lower baseline HbA1c (< 8%). Although few studies reported data on harms of SMBG, the frequency of mild to moderate hypoglycemia may be increased with frequent SMBG, and quality of life may be slightly decreased with intensive SMBG compared to standard care.

## GRADE-INFORMED FRAMEWORK

The HERC develops recommendations by using the concepts of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. GRADE is a transparent and structured process for developing and presenting evidence and for carrying out the steps involved in developing recommendations. There are four elements that determine the strength of a recommendation, as listed in the table below. The HERC reviews the evidence and makes an assessment of each element, which in turn is used to develop the recommendations presented in the coverage guidance box. Balance between desirable and undesirable effects, and quality of evidence, are derived from the evidence presented in this document, while estimated relative costs, values and preferences are assessments of the HERC members.

Indication	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
SMBG for Type 1 or Type 2 MDII-requiring Diabetes	Benefits likely outweigh harms, given evidence from DCCT of improved outcomes with tighter glucose control, and the need for SMBG to achieve tighter control	None	Moderate, although costs may be offset by tighter control resulting in improved outcomes	Minimal variability in preference for SMBG supplies	SMBG supplies are recommended for coverage for insulin-requiring diabetes <i>Strong recommendation</i>
SMBG for Type 2 Diabetes not requiring MDII	No clinically important benefit overall, some clinically significant benefit in intermediate outcome in patients with poorer control, and when delivered in concert with a structured education and feedback program	High	Moderate	Moderate variability	SMBG supplies to allow testing no more than once weekly are recommended for coverage for Type 2 diabetes patients not requiring MDII with HbA1c >8.0%, when they are accompanied by a structured education and feedback program <i>Strong recommendation</i>

Note: GRADE framework elements are described in Appendix A

## POLICY LANDSCAPE

There were 244 quality measures that pertain to diabetes in some way that were identified when searching the [National Quality Measures Clearinghouse](#). None specifically address the use or frequency of self-monitoring of blood glucose. The following measures pertain to the testing of HbA1c or diabetes control:

Developer: HRSA Health Disparities Collaboratives: Diabetes Collaborative - Federal Government Agency [U.S.]. These have not been endorsed by the National Quality Forum.

- Diabetes mellitus: average HbA1c value for diabetic patients in the clinical information system.
- Diabetes mellitus: percent of patients with 2 HbA1c's in the last year (at least 3 months apart).

Developer: National Committee for Quality Assurance (NCQA). HEDIS 2012: Healthcare Effectiveness Data and Information Set. Vol. 1, narrative. Washington (DC): National Committee for Quality Assurance (NCQA); 2011. All but the last of these have been endorsed by the National Quality Forum.

- Comprehensive diabetes care: percentage of members 18 to 75 years of age with diabetes (type 1 and type 2) who had hemoglobin A1c (HbA1c) testing.
- Comprehensive diabetes care: percentage of members 18 to 75 years of age with diabetes (type 1 and type 2) whose most recent hemoglobin A1c (HbA1c) level is greater than 9.0% (poorly controlled).
- Comprehensive diabetes care: percentage of members 18 to 75 years of age with diabetes (type 1 and type 2) whose most recent hemoglobin A1c (HbA1c) level is less than 8.0% (controlled).
- Comprehensive diabetes care: percentage of members 18 to 75 years of age with diabetes (type 1 and type 2) whose most recent hemoglobin A1c (HbA1c) level is less than 7.0% (controlled).

Developer: AHRQ quality indicators. Guide to prevention quality indicators: hospital admission for ambulatory care sensitive conditions [version 3.1]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2007 Mar 12. 59 p. (AHRQ Pub; no. 02-R0203). All of these have been endorsed by the National Quality Forum.

- Diabetes mellitus: hospital admission rate for uncontrolled diabetes.
- Diabetes mellitus: hospital admission rate for long-term complications.

- Diabetes mellitus: hospital admission rate for short-term complications.

### COMMITTEE DELIBERATIONS – HTAS

Based on expert testimony, the Health Technology Assessment Subcommittee decided to recommend coverage for 100 testing strips per 90 days for patients with Type 2 diabetes who meet certain criteria which may increase the need for monitoring. Of the criteria suggested by the experts, the Subcommittee decided not to include an exception for elderly patients because choosing an age to define elderly would be somewhat arbitrary and because this population would most likely meet the other criteria for receiving additional strips. The Subcommittee did include exceptions to cover the higher number of strips for Type 2 diabetes patients who: are newly diagnosed and receiving diabetes education, changing treatment regimens, have unexplained or new onset hyperglycemia, have a recent history of hypoglycemia, have comorbid conditions affecting diabetic control, have microvascular or macrovascular complications of diabetes, are on basal (once daily) insulin, or are on systemic corticosteroid therapy.

### COMMITTEE DELIBERATIONS – VBBS

For coverage under the Oregon Health Plan, the subcommittee recommended 50 strips per 90 days for patients with type 2 diabetes and complicating factors because the studies justifying the use of additional test strips for this population used a maximum of 12 strips per month.

A new guideline was proposed for the Prioritized List.

### HERC DELIBERATIONS

HERC reviewed the draft coverage guidance on 10/10/2013 and 12/5/2013. After extensive discussion regarding evidence, implementation concerns and public input, the HERC decided to simplify the Coverage Guidance box language and associated guideline note with regards to type 2 diabetic patients not requiring multiple daily insulin injections. For these patients, 50 strips (and related supplies) are recommended at diagnosis, with an additional 50 strips per 90 days recommended for those on medications which may cause hypoglycemia. In addition, based on public testimony and clinical judgment, the HERC recommended coverage for an additional 50 strips any time there is an acute change in glycemic control or active diabetic medication adjustment. In addition, the HERC modified the recommendation on structured education and feedback to clarify that a structured education and feedback program is recommended for coverage specifically for patients prescribed test strips and to remove the implication that participation in such a program would be required in order to receive test strips and supplies.

For coverage under the Oregon Health Plan, the HERC approved a guideline note based on the language in the Coverage Guidance.

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

The Center is not engaged in rendering any clinical, legal, business or other professional advice. The statements in this document do not represent official policy positions of the Center. Researchers involved in preparing this document have no affiliations or financial involvement that conflict with material presented in this document.

## Appendix A. GRADE Element Descriptions

Element	Description
Balance between desirable and undesirable effects	The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted
Quality of evidence	The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted
Resource allocation	The higher the costs of an intervention—that is, the greater the resources consumed—the lower the likelihood that a strong recommendation is warranted
Values and preferences	The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a weak recommendation is warranted

### Strong recommendation

***In Favor:*** The subcommittee is confident that the desirable effects of adherence to a recommendation outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

***Against:*** The subcommittee is confident that the undesirable effects of adherence to a recommendation outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences.

### Weak recommendation

***In Favor:*** the subcommittee concludes that the desirable effects of adherence to a recommendation probably outweigh the undesirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

***Against:*** the subcommittee concludes that the undesirable effects of adherence to a recommendation probably outweigh the desirable effects, considering the quality of evidence, cost and resource allocation, and values and preferences, but is not confident.

### Quality of evidence across studies for the treatment/outcome

***High*** = Further research is very unlikely to change our confidence in the estimate of effect.

***Moderate*** = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

***Low*** = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

***Very low*** = Any estimate of effect is very uncertain.

## Appendix B. Applicable Codes

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD-9 Diagnosis Codes</b>	
249	Secondary Diabetes Mellitus
250	Diabetes Mellitus
<b>ICD-9 Volume 3 (Procedure Codes)</b>	
None	
<b>CPT Codes</b>	
83036	Hemoglobin; glycosylated (A1C)
83037	Hemoglobin; glycosylated (A1C) by device cleared by FDA for home use
97802-97804	Medical nutrition therapy
98960-98962	Education and training for patient self-management by a qualified, nonphysician health care professional using a standardized curriculum, face-to-face, with the patient (could include caregiver/ family) each 30 minutes
99078	Physician educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)
<b>HCPCS Level II Codes</b>	
A4233-6	Batteries for home blood glucose monitors
A4253	Blood Glucose test strips, box of 50
A4255	Platforms for home blood glucose monitor, 50/box
A4256	Calibrator solutions/chips
A4258	Spring-powered device for lancet, each
A4259	Lancets, per box of 100
E0607	Blood glucose monitor
E2100	Blood glucose monitor with voice synthesizer
E2101	Blood glucose monitor with integrated lancer
G0108-G0109	Diabetes outpatient self-management training services
G0270-G0271	Medical nutrition therapy; reassessment and subsequent intervention(s) following second referral in same year for change in diagnosis, medical condition or treatment regimen (including additional hours needed for renal disease)
S9140	Diabetic management program, follow-up visit to non-MD provider
S9141	Diabetic management program, follow-up visit to MD provider

Note: Inclusion on this list does not guarantee coverage

# Appendix C. HERC Guidance Development Framework – SMBG Indications

## SMBG for Type 1 or Type 2 MDII-requiring Diabetes



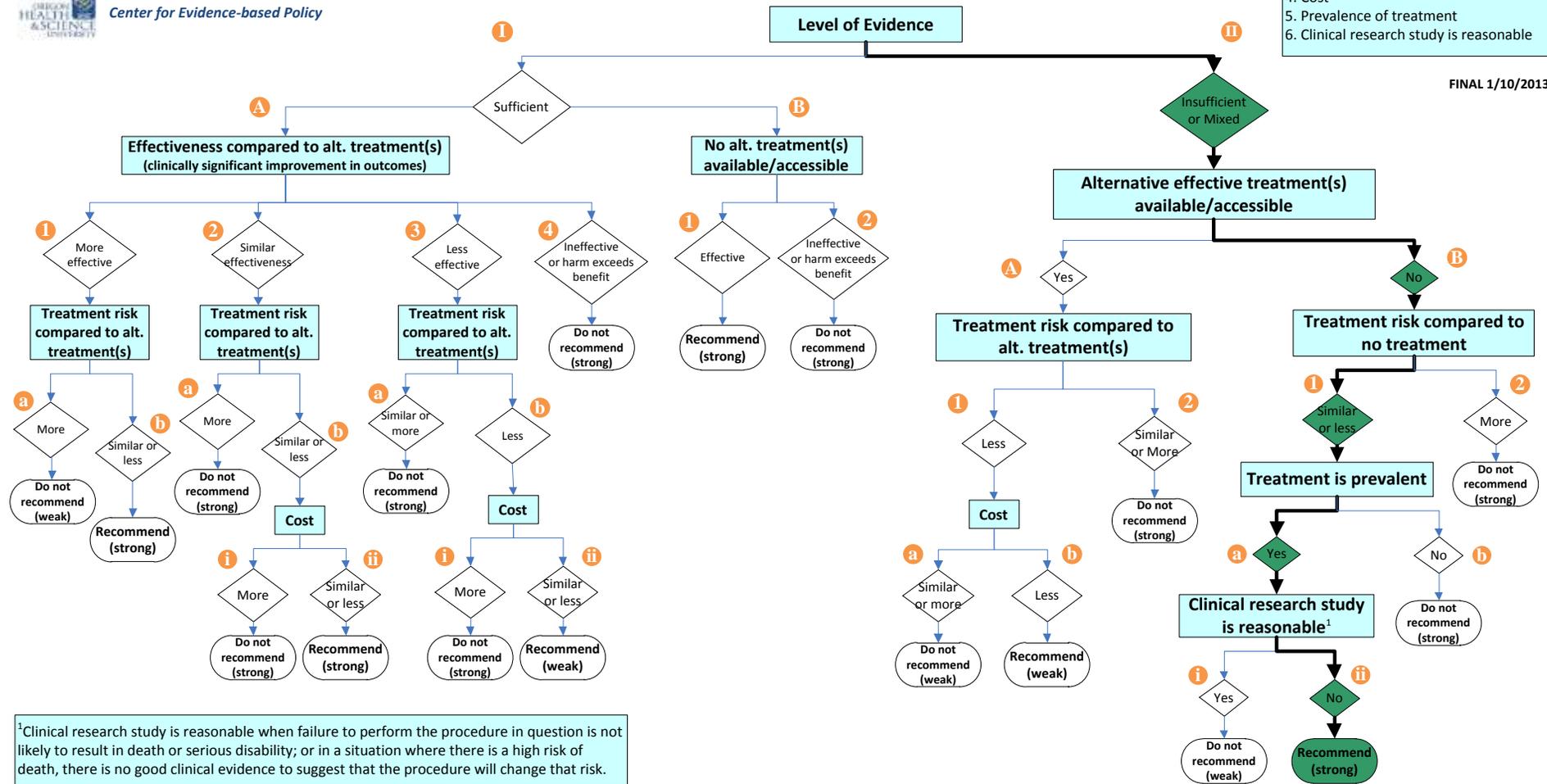
### HERC Guidance Development Framework

Refer to HERC Guidance Development Framework Principles for additional considerations



- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

FINAL 1/10/2013



# SMBG for Type 2 Diabetes Not Requiring MDII: HbA1c > 8%



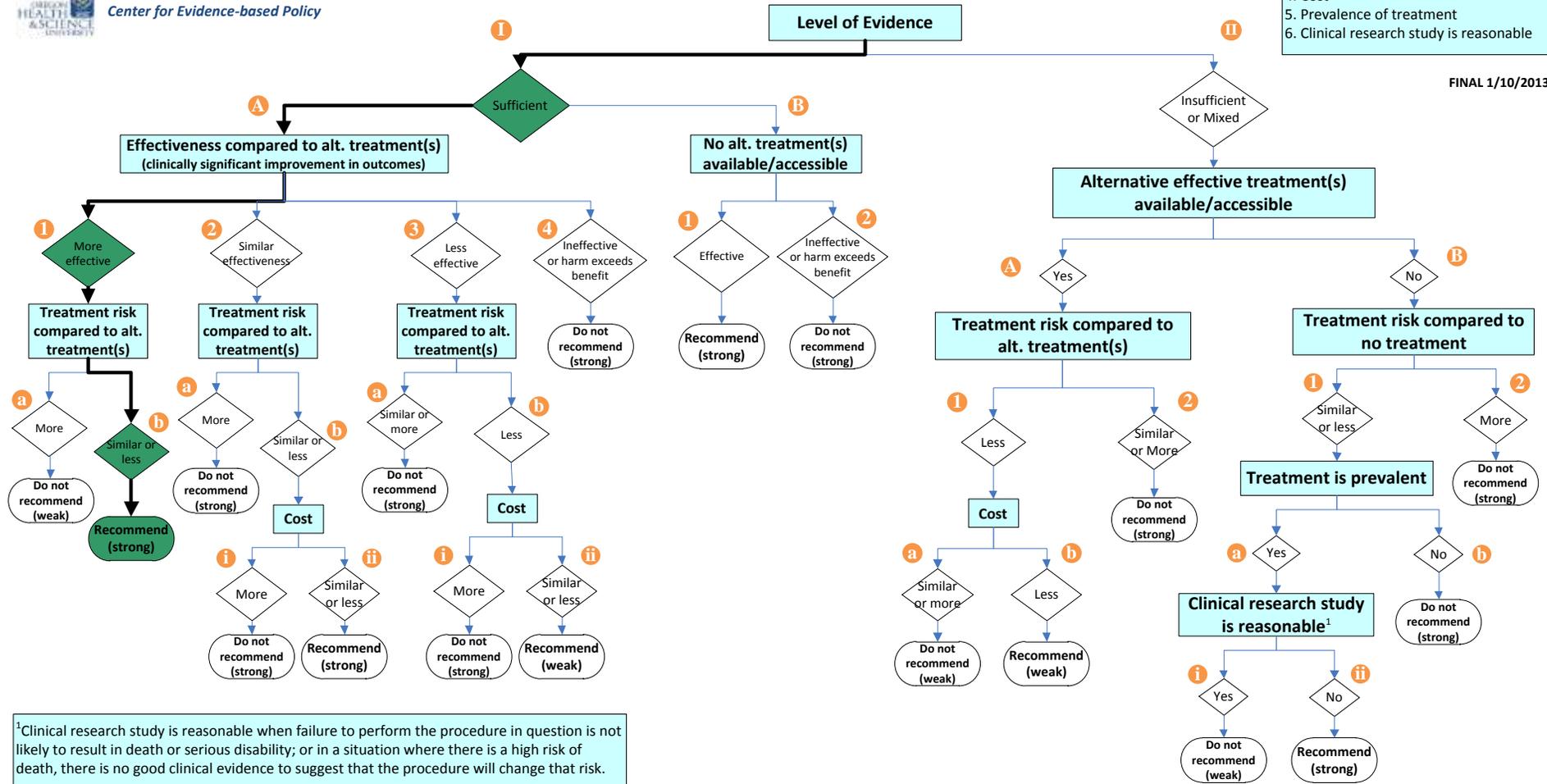
Center for Evidence-based Policy

## HERC Guidance Development Framework

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- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

FINAL 1/10/2013



# SMBG for Type 2 Diabetes Not Requiring MDII: HbA1c ≤ 8



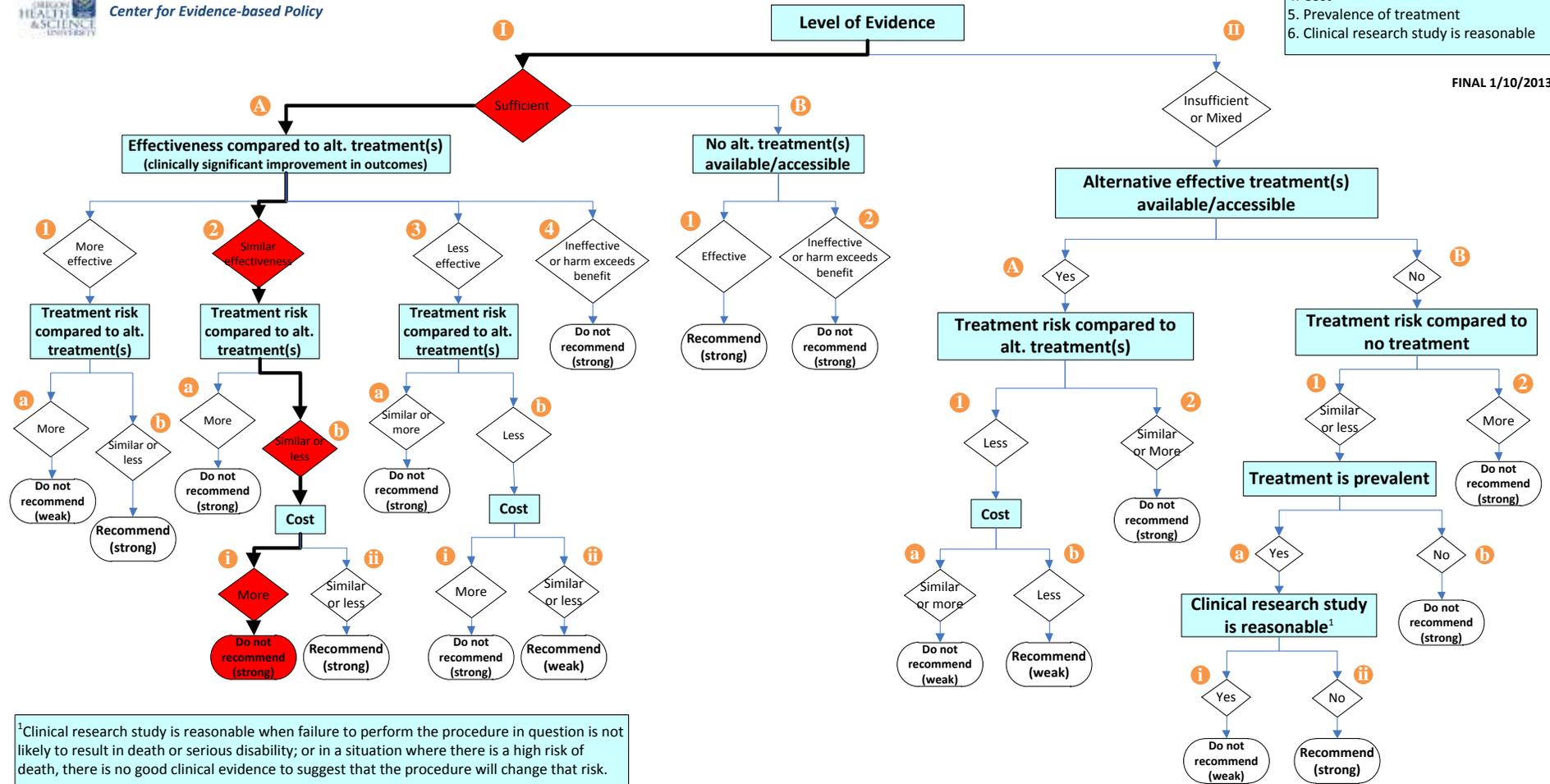
Center for Evidence-based Policy

## HERC Guidance Development Framework

Refer to HERC Guidance Development Framework Principles for additional considerations

- Decision Point Priorities**
1. Level of evidence
  2. Effectiveness & alternative treatments
  3. Harms and risk
  4. Cost
  5. Prevalence of treatment
  6. Clinical research study is reasonable

FINAL 1/10/2013



**HTAS Recommendation:** Reaffirm the existing coverage guidance and reconsider the need to update it during the regular two-year review cycle.

**Bottom Line:** Several new systematic reviews and meta-analyses have examined the effects of SMBG for patients with T2DM on non-insulin therapies. These reviews all suggest a small improvement in A1c (0.2% to 0.3%) with use of SMBG. Evidence of clinical outcomes is lacking. Available guidelines support the use of SMBG in patients on multiple daily insulin injections and in pregnant women.

**Scope Statement**

<b>Population description</b>	Children, adolescents, and adults with type 2 diabetes mellitus who are not using multiple daily insulin injections (MDII)  <i>Population scoping notes: None</i>
<b>Intervention(s)</b>	Self-monitoring of blood glucose (SMBG), with or without structured education and feedback programs.  <i>Intervention exclusions: None</i>
<b>Comparator(s)</b>	No routine monitoring using SMBG, periodic monitoring of HbA1c
<b>Outcome(s) (up to five)</b>	<b>Critical:</b> Severe morbidity (e.g. microvascular and macrovascular complications), severe hypoglycemia <sup>1</sup>  <b>Important:</b> Quality-of-life, change in HbA1c, hyperosmolar hyperglycemic state  <i>Considered but not selected for GRADE table: Hospitalizations, emergency department visits, all-cause mortality.</i>

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<sup>1</sup> “An event requiring assistance of another person to actively administer carbohydrate, glucagons, or other resuscitative actions.” (ADA Workgroup on Hypoglycemia, 2005)

<b>Key questions</b>	<ol style="list-style-type: none"> <li>1. What is the effectiveness of SMBG in improving outcomes in children, adolescents, and adults with type 2 diabetes mellitus who are not using multiple daily insulin injections (MDII)?</li> <li>2. What is the evidence of harms associated with SMBG in this population?</li> <li>3. Is there evidence of differential effectiveness of SMBG based on: <ol style="list-style-type: none"> <li>a. Type of treatment (i.e. diet and exercise, oral antidiabetic agents, basal insulin, non-insulin injectables)</li> <li>b. Frequency of testing</li> <li>c. Degree of glycemic control at baseline</li> <li>d. Association with a structured education and feedback program</li> </ol> </li> <li>4. What are appropriate quantities of testing supplies for this population, and what factors should trigger allowances for additional supplies (e.g. infection, driving, etc.)</li> </ol>
<b>Special Considerations – Rescanning</b>	<p>We will not search the literature on people with Type I diabetes or Type II diabetes with multiple daily insulin injections, as these are well-established and had a strong recommendation in the last coverage guidance.</p>

### Scanning Results

1. American Diabetes Association. (2012). Standards of medical care in diabetes—2012. *Diabetes Care*, 35(Suppl 1), S11-63.

Citation 1 is a clinical practice guideline from the American Diabetes Association. The ADA offers the following recommendations regarding SMBG:

- SMBG should be carried out three or more times daily for patients using multiple insulin injections or insulin pump therapy. (B)
- 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)
- To achieve postprandial glucose targets, postprandial SMBG may be appropriate. (E)

- When prescribing SMBG, ensure that patients receive initial instruction in, and routine follow-up evaluation of, SMBG technique and their ability to use data to adjust therapy. (E)

B recommendations are based on data from well-conducted cohort studies. E recommendations are based on expert opinion/consensus.

2. Breland, J. Y., McAndrew, L. M., Burns, E., Leventhal, E. A., & Leventhal, H. (2013). Using the common sense model of self-regulation to review the effects of self-monitoring of blood glucose on glycemic control for non-insulin-treated adults with type 2 diabetes. *Diabetes Educator*, 39(4), 541-59.

Citation 2 is a SR of 26 studies of SMBG for adults with T2DM on non-insulin therapies. The studies were published between 2007 and 2011. Eleven of the included trials were RCTs. These trials were heterogeneous and the results were mixed. Some trials found that SMBG + education resulted in improvement in A1c, but other trials found that education alone achieved similar reductions. Clinical outcomes are not reported.

3. Canadian Agency for Drugs and Technologies in Health (CADTH). (2013). *Blood glucose monitors and test strips: a review of the comparative clinical evidence and cost-effectiveness — an update*. Ottawa: CADTH.

Citation 3 is a comparative study of the accuracy of different glucometers. It would not be relevant to an update of this coverage guidance.

4. Farmer, A. J., Perera, R., Ward, A., Heneghan, C., Oke, J., Barnett, A. H., ... O'Malley, S. (2012). Meta-analysis of individual patient data in randomised trials of self monitoring of blood glucose in people with non-insulin treated type 2 diabetes. *British Medical Journal*, 344, e486.

Citation 4 is a patient-level meta-analysis of the effects of SMBG for non-insulin treated adults with T2DM. The authors conclude that SMBG is not associated with clinically meaningful improvements in diabetic control in this population.

5. Hou, Y. Y., Li, W., Qiu, J. B., & Wang, X. H. (2014). Efficacy of blood glucose self-monitoring on glycemic control in patients with non-insulin-treated type 2 diabetes: a meta-analysis. *International Journal of Nursing Sciences*, 1(2), 191-195.

Citation 5 is a SR and MA of 7 RCTs of SMBG in non-insulin treated adults with T2DM. The authors conclude that SMBG in conjunction with diabetic education results in improvements in A1c of 0.42%. SMBG without diabetic education did not improve A1c.

6. Kesavadev, J., Sadikot, S., Wangnoo, S., Kannampilly, J., Saboo, B., Aravind, S. R., ... Vishwanathan V. (2014). Consensus guidelines for glycemic monitoring in type 1/type 2 & GDM. *Diabetes & Metabolic Syndrome*, 8(3), 187-95.

Citation 6 is a clinical practice guideline from Diabetes India. It provides 13 recommendations regarding the use of SMBG. All but one of the recommendations is based on expert opinion and the remaining recommendation is based on observational studies.

7. Malanda, U. L., Welschen, L. M. C., Riphagen, I. I., Dekker, J. M., Nijpels, G., Bot, S. D. M. (2012). Self-monitoring of blood glucose in patients with type 2 diabetes mellitus who are not using insulin. *Cochrane Database of Systematic Reviews* 2012, Issue 1. A rt. No.: CD005060. DOI: 10.1002/14651858.CD005060.pub3.

Citation 7 is a Cochrane review of SMBG for patients with T2DM not on insulin. It includes 12 RCTs spanning more than 3,200 patients. The authors conclude that in this population, SMBG results in slight improvements in A1c at 6 months, but these improvements wane by 12 months. Furthermore, SMBG was not associated with improved patient satisfaction or health-related quality of life.

8. McIntosh, B., Yu, C., Lal, A., Chelak, K., Cameron, C., Singh, S. R., & Dahl, M. (2010). Efficacy of self-monitoring of blood glucose in patients with type 2 diabetes mellitus managed without insulin: a systematic review and meta-analysis. *Open Medicine*, 4(2), e102-e113.

Citation 8 is a SR and MA of the effects of SMBG in patients with T2DM on oral antidiabetic agents. They conclude that SMBG is associated with small improvements in A1c (0.25%) at 6 months. SMBG appeared to have no effect on quality of life, hypoglycemia, long-term complications of DM2, or mortality.

9. Minet, L., Moller, S., Vach, W., Wagner, L., & Henriksen, J. E. (2010). Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials. *Patient Education and Counseling*, 80(1), 29-41.

Citation 9 is a SR and MA of over 40 trials of self-care management interventions in T2DM. It does not explicitly address the use of SMBG.

10. Moy, F. M., Ray, A., & Buckley, B. S. (2014). Techniques of monitoring blood glucose during pregnancy for women with pre-existing diabetes. *Cochrane Database of Systematic Reviews*, Issue 4. Retrieved from <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD009613.pub2/epdf>

Citation 10 is a Cochrane review of SMBG for pregnant women with pre-existing diabetes. Only 2 of the included studies compared SMBG with usual care. Both studies

were small and published in the early 1980s. There were no significant differences in maternal or fetal outcomes in these studies.

11. NHS. (2013). *When is self monitoring of blood glucose recommended in type 2 diabetes?* Regional Drug and Therapeutics Centre. Retrieved from <http://www.medicinesresources.nhs.uk/GetDocument.aspx?pagelId=760035>

Citation 11 summarizes NICE guidance on SMBG for patients with T2DM. The key recommendations are:

Self Monitoring of blood glucose should only be offered as an integral part of diabetes self-management education, and should be available to:

- Those on insulin treatment
- Those on oral glucose lowering medications who may be at risk of hypoglycemia
- Assess the impact of lifestyle and medication changes on blood glucose control
- Monitor changes during acute inter current illness
- Ensure safety during activities such as driving

Therefore patients with type 2 diabetes who are controlled by diet, metformin or glitazones should not routinely be offered SMBG.

12. NICE. (2015). *Diabetes in pregnancy: Management of diabetes and its complications from preconception to the postnatal period*. London: NICE. Retrieved from <http://www.nice.org.uk/guidance/ng3/resources/diabetes-in-pregnancy-management-of-diabetes-and-its-complications-from-preconception-to-the-postnatal-period-51038446021>

Citation 12 is a NICE guideline on the use of SMBG in pregnancy. It recommends that SMBG should be used in a variety of scenarios, including women with pre-existing diabetes and for women with a history of gestational diabetes in a prior pregnancy.

13. St John, A., Davis, W. A., Price, C. P., & Davis, T. M. (2010). The value of self-monitoring of blood glucose: a review of recent evidence. *Journal of Diabetes and Its Complications*, 24(2), 129-141.

Citation 13 is a SR and MA of 6 RCTs of SMBG for patients with T2DM treated with non-insulin therapies. SMBG was associated with a small improvement in A1c (0.22%). They note that this is consistent with the findings of observational trials.

## Methods

### *Search Strategy*

A full search of the core sources was conducted to identify systematic reviews, meta-analyses, technology assessments, and clinical practice guidelines using the terms “self monitor glucose.” Searches of core sources were limited to citations published after 2009.

The core sources searched included:

- Agency for Healthcare Research and Quality (AHRQ)
- Blue Cross/Blue Shield Health Technology Assessment (HTA) program
- BMJ Clinical Evidence*
- Canadian Agency for Drugs and Technologies in Health (CADTH)
- Cochrane Library (Wiley Interscience)
- Hayes, Inc.
- Medicaid Evidence-based Decisions Project (MED)
- National Institute for Health and Care Excellence (NICE)
- Tufts Cost-effectiveness Analysis Registry
- Veterans Administration Evidence-based Synthesis Program (ESP)
- Washington State Health Technology Assessment Program

A MEDLINE® (Ovid) search was conducted to identify systematic reviews, meta-analyses, and technology assessments published after the search dates of original evidence sources. The search was limited to publications in English published after 2008.

Searches for clinical practice guidelines were limited to those published since 2010. A search for relevant clinical practice guidelines was also conducted, using the following sources:

- Australian Government National Health and Medical Research Council (NHMRC)
- Centers for Disease Control and Prevention (CDC) – Community Preventive Services
- Institute for Clinical Systems Improvement (ICSI)
- National Guidelines Clearinghouse
- New Zealand Guidelines Group
- NICE
- Scottish Intercollegiate Guidelines Network (SIGN)
- United States Preventive Services Task Force (USPSTF)
- Veterans Administration/Department of Defense (VA/DOD)

*Inclusion/Exclusion Criteria*

Studies were excluded if they were not published in English, did not address the scope statement, or were study designs other than systematic reviews, meta-analyses, technology assessment, or clinical practice guidelines.

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