

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

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

DRAFT AS POSTED FOR PUBLIC COMMENT 2/28/2013

HERC COVERAGE GUIDANCE

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. Such coverage should include a structured education and feedback program for self-monitoring of blood glucose (*strong recommendation*).

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 (*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. Seven 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	Expert Input	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

COMMITTEE DELIBERATIONS – VBBS

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.

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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

CODES	DESCRIPTION
ICD-9 Diagnosis Codes	
249	Secondary Diabetes Mellitus
250	Diabetes Mellitus
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
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)
HCPCS Level II Codes	
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 lancing
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



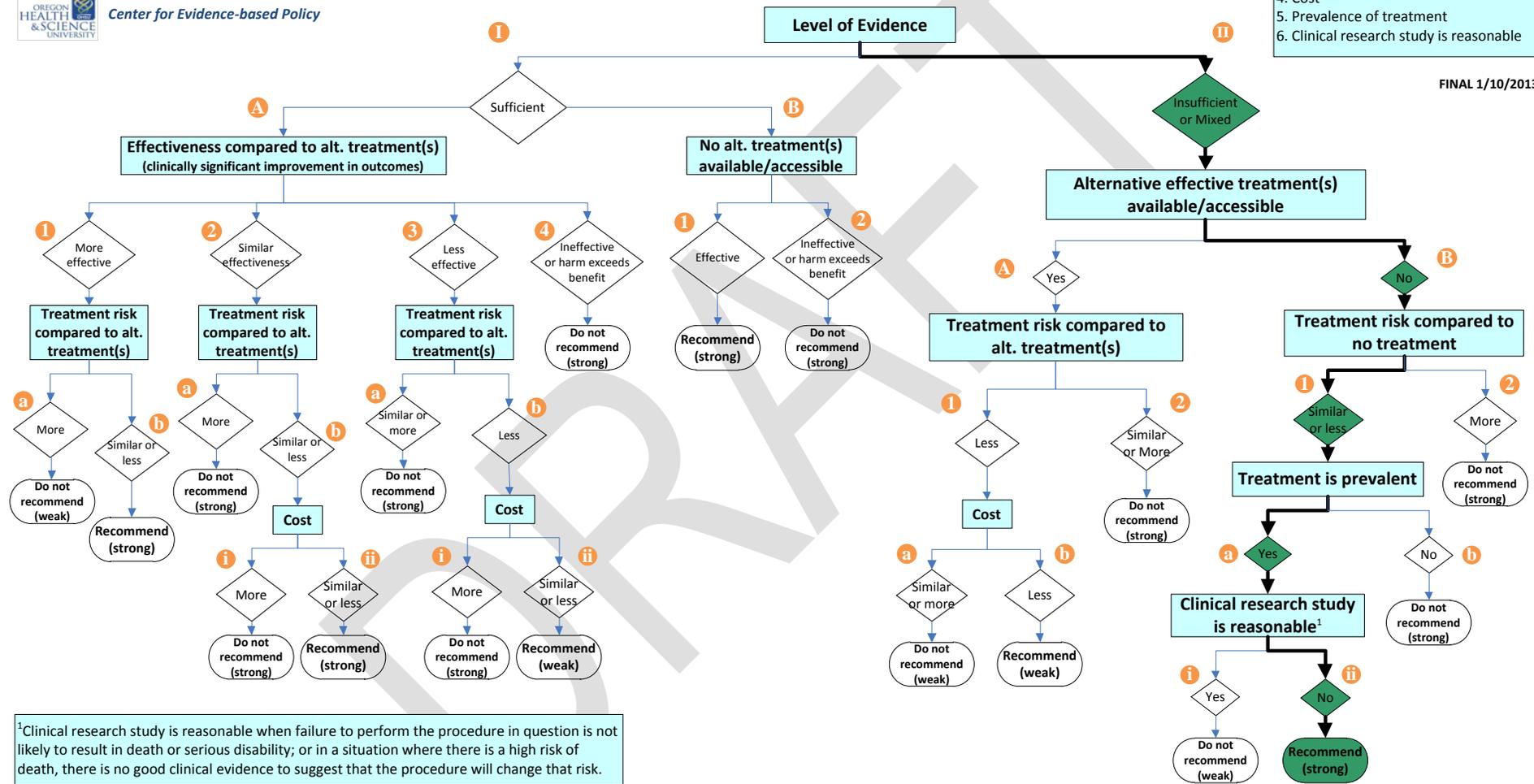
HERC Guidance Development Framework

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%

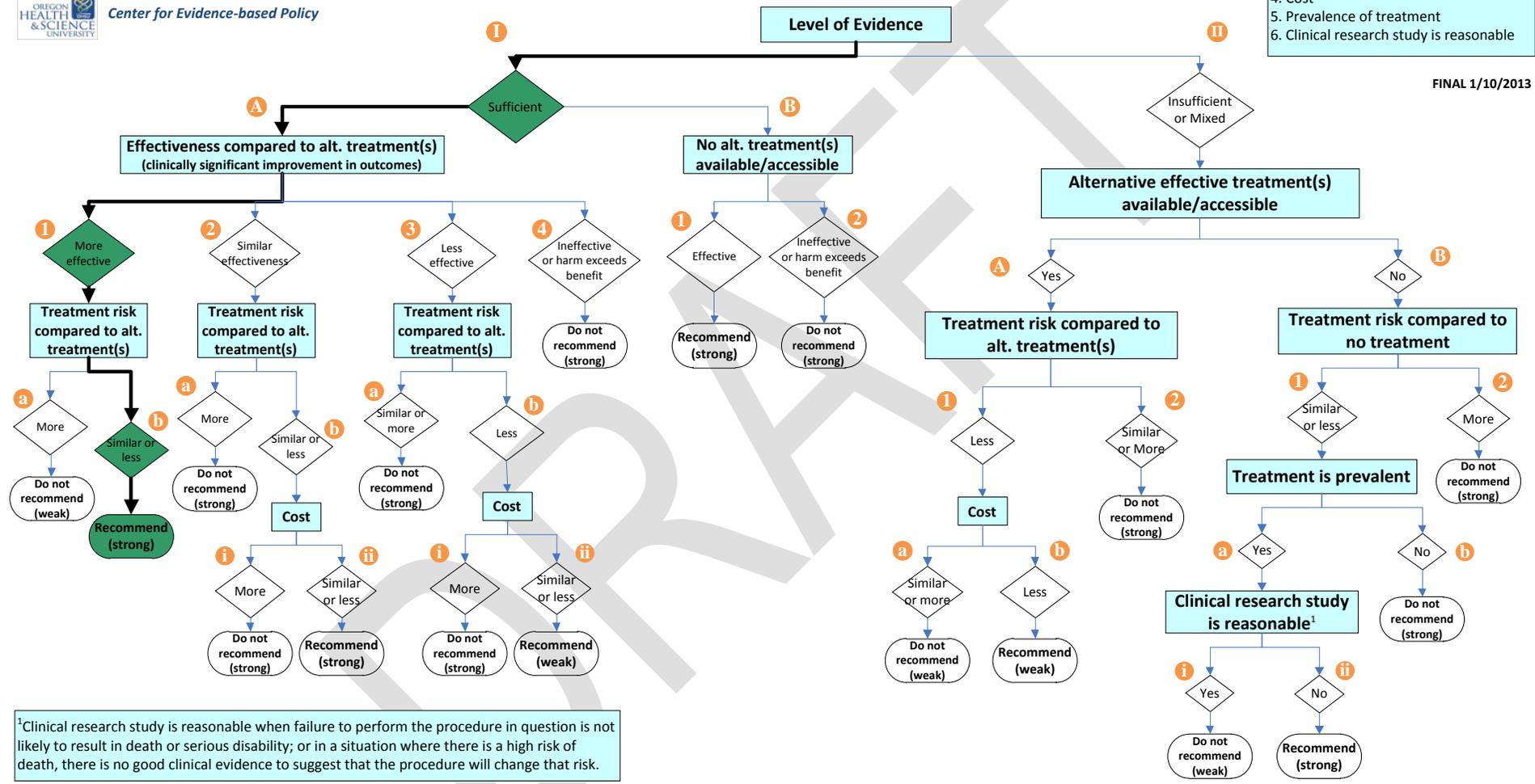


HERC Guidance Development Framework

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

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



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

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