



Health Evidence Review Commission

December 5, 2013

2:00-5:00 PM

**Meridian Park Hospital
Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR 97062**

Section 1.0

Call to Order

AGENDA
HEALTH EVIDENCE REVIEW COMMISSION

Meridian Park Room 117

December 5, 2013

2:00-5:00 pm

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	2:00 PM	Call to Order	Som Saha	
2	2:05 PM	Approval of Minutes (10/10/2013)	Som Saha	X
3	2:10 PM	Director's Report	Darren Coffman	
4	2:15 PM	Health Technology Assessment Subcommittee Coverage Guidances for HERC review 1) Self-monitoring of blood glucose 2) Carotid Endarterectomy	Alissa Craft Wally Shaffer Alison Little	X
5	4:00 PM	Evidence-based Guidelines Subcommittee Coverage Guidances for HERC review 1) ADHD	Wiley Chan Cat Livingston Alison Little	X
6	4:45 PM	Next Steps • Schedule next meeting – January 9, 2014 Meridian Park Room 117 B&C	Som Saha	
7	4:50 PM	Public Comment		
8	5:00 PM	Adjournment	Som Saha	

Minutes

HEALTH EVIDENCE REVIEW COMMISSION
Meridian Park Hospital
Community Health Education Center Room 117B&C
Tualatin, OR 97062
October 10, 2013

Members Present: Som Saha, MD, Chair; Alissa Craft, DO, MBA, Vice-Chair (via teleconference); Lisa Dodson, MD; James Tyack, DMD; Beth Westbrook, PsyD; Wiley Chan, MD; Irene Crowell, RPh; Gerald Ahmann, MD; Mark Gibson; Leda Garside, RN; Susan Williams, MD.

Members Absent: Vern Saboe, DC

Staff Present: Darren Coffman; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Dorothy Allen.

Also Attending: Denise Taray, DMAP; Alison Little, MD, MPH & Shannon Vandegriff, OHSU CeBP; David Topp & Mark Swinton, Abbot; Jessie Little, Actuarial Services Unit of OHA; *Farahnaz Joarder, OHSU; *Paul Radensky, MD, McDermott Will & Emery; Elana Scharff, Tuality; James Clark, Roche; Dianne Danowski-Smith, Oregon Healthwire; Rhonda Busek & Lori Coyner, OHA; Bill Struyk, Johnson & Johnson; Ellen Lowe, OAHHS; *BJ Cavnor, One in Four Chronic Health; Jim Hoover, Bayer; *Laura Keller, American Diabetes Association; Alan Ackmann, Allergan; Rachel Seltzer, OHSU/PSU; *Michelle Grove, ANP, The Portland Clinic.

**Provided testimony*

Call to Order

Som Saha, Chair of the Health Evidence Review Commission (HERC), called the meeting to order at 1:30 pm. Role was called.

Approval of Minutes

MOTION: To approve the minutes of the August 10, 2013 meeting as presented.
CARRIES 11-0.

Director's Report

Darren Coffman said staff have been getting frequent requests to allow audience participation via conference call. Commissioners expressed their wish to have participation and testimony in person. Citizens who cannot physically attend a meeting may, per posted policy, submit written testimony (must be received 7 days in advance of the meeting to allow Commissioner's sufficient review time). Special cases require a consultation with the Chair and Director.

Update on Cover Oregon and the Medicaid Expansion under the Affordable Care Act

Rhonda Busek, BS, MBA, Deputy Director, DMAP, OHA, gave a presentation titled "*Better Health, Better Care, Lower Costs.....For Everyone.*" The complete presentation is available here: [Meeting materials handout](#)

Ms. Busek's presentation focused on OHA's efforts to improve how health care is delivered, highlighting Oregon Health Plan's (OHP) Coordinated Care Organizations. She also spoke about OHA's efforts to implement federal health reform, which includes expanding OHP to more families, and implementing the health exchange.

CCO Performance Metrics

Lori Coyner, MA, Director of Accountability and Quality, OHA, gave a presentation titled "*OHA Quality and Accountability: Metrics for Coordinated Care Organizations.*" The complete presentation is available here: [Meeting materials handout](#)

Ms. Coyner shared details about the health system transformation changes. Metrics are meant to help achieve OHA'S triple aim by measuring transformation of the Health Care System with a focus on outcomes.

Subcommittee Reports

Value-based Benefits Subcommittee (VbBS) Report

[Meeting materials, pages 18-118](#)

Ariel Smits, Cat Livingston and Lisa Dodson reported the VbBS met earlier in the day, October 10, 2013. Each helped to summarize a number of topics discussed.

Recommendations for interim changes to the Prioritized List, for implementation 4/1/14 unless otherwise indicated, include:

Code movement/placement recommendations:

- A number of straightforward coding changes
- Add placement of 106 2014 CPT codes (6 codes on transcatheter placement of an intravascular stent(s) and mechanical chest wall oscillation require further research and will be brought forward to a future meeting)
- Add codes for the diagnosis and treatment of femoroacetabular impingement (FAI) syndrome to a covered line with a new guideline
- Add coverage of intraocular steroid procedures for treatment of posterior uveitis and central retinal vein occlusion with two new guidelines
- Add use of extracorporeal photophoresis for cutaneous T-cell lymphoma and chronic cutaneous graft-vs-host disease with a new guideline

Guideline changes recommendations:

- Update the cervical cancer screening guideline to reflect the most recent national guidelines

- Add a new guideline for upper endoscopy for GERD and heartburn symptoms
- Add a new guideline outlining coverage of prenatal genetic testing
- Add a new guideline for tonsillectomy for treatment of sleep apnea (OSA) in children. Amend the existing tonsillectomy guideline to remove OSA.

Biennial review changes, tentative effective date: January 1, 2016:

- Merge lines for open wound of eardrum and chronic otitis media lines, renamed: “CHRONIC OTITIS MEDIA; OPEN WOUND OF EAR DRUM”

MOTION: To accept the VbBS recommendations as stated. See the VbBS minutes of 10/10/13 for a full description. Carries: 11-0.

Health Technology Assessment Subcommittee (HTAS) Report
[Meeting materials, pages 119-204](#)

Alison Little presented all the proposed coverage guidances from HTAS.

Topic: Self-monitoring of Blood Glucose (SMBG) for Type 1 and Type 2 Diabetes Mellitus (DM)

Evidence summary presented:

- No studies address SMBG for Type 1 DM or Type 2 DM requiring multiple daily insulin injections (MDII)
- For Type 2 DM not requiring MDII
 - No studies address impact of SMBG on clinical outcomes
 - SMBG decreases HbA1c by mean of -0.21%
 - Accepted value of clinically important change = -0.5%
 - No difference in HbA1c between testing frequency of 3 to 7X/week and 1X/week
 - Higher baseline HbA1c (≥ 8%) have greater reductions (-0.27% to -1.23%)
 - Mild to moderate hypoglycemia increased with more frequent SMBG, resulting in decreased quality of life

Coffman reviewed the VbBS's OHP implementation recommendations:

- No limitation proposed for type 1 diabetes or type 2 diabetes requiring multiple daily insulin injections or those patients with a HbA1c greater than 8 percent.
- Guideline allows coverage for 50 test strips per 90 days for certain patients with type 2 diabetes and complicating factors (but who do not require multiple daily insulin injections). This recommendation differs from 100 test strips per 90 days recommended in coverage guidance.
- Evidence supporting the recommendation for 50 strips was based on studies using 12 strips/month
- Concern about giving the impression that testing is not important, when it is important for many patients

Proposed coverage guidance:

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).

Additional supplies for self-monitoring of blood glucose, up to 100 test strips for 90 days, is recommended for coverage for the following patients with Type 2 diabetes (*weak recommendation*):

- Patients newly diagnosed and receiving diabetes education
- Patients changing treatment regimens
- Patients with unexplained or new onset hyperglycemia
- Patients with recent history of hypoglycemia
- Patients with comorbid conditions affecting diabetic control
- Patients with microvascular or macrovascular complications of diabetes
- Patients on basal (once daily) insulin
- Patients on systemic corticosteroid therapy

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.

Dodson discussed the public perception that this coverage guidance was de-emphasizing diabetes care. That is not the Commission's intent. In response, HERC's leadership are bringing forward a reordering of the paragraphs of the coverage guidances to stress the importance of appropriate care of patients with diabetes. She was clear that test strips should be dispensed in a way that agrees with the evidence and that testing alone is small piece of managing the chronic disease.

She asserted that the cost for testing is staggering. Given that there are 262,000 Oregonians with diabetes, a quick calculation assuming each patient testing 3 times a day would result in costs of about \$300 million a year. It is a great cost without any clear evidence of effectiveness of reducing morbidity or mortality.

Editor's Note: This calculation assumes a cost of \$1 per strip; using the Medicaid fee-for-service reimbursement of \$0.65/strip calculates to about \$186 million per year.

Mark Gibson stated that HERC's task is to make policy based on the best available evidence, and to inform insurers, both public and private. We should stop paying for interventions that do not work. In the case of the presented coverage guidance, the letter of the evidence was ignored. The proposed guideline for OHP runs closer to the evidence; approving two such different standards sets up a disparity between Medicaid and privately insurance patients.

The evidence does show that increased testing has a diminishing effect on quality of life and perhaps increases hypoglycemia. The Medicaid policy proposed is a more health producing policy and is more economical. Policies like this uphold the Health Policy Board's Triple Aim concepts of:

- Improve the lifelong health of all Oregonians
- Increase the quality, reliability and availability of care for all Oregonians
- Lower or contain the cost of care so it is affordable for everyone

Saha added that the intent of each coverage guidance is to give a recommendation, based on the evidence, to the coverage decision makers. The decision-makers' challenge is to weigh the recommendations and to create their internal policy, exactly as VbBS has done with their OHP deliberations.

Alissa Craft, HTAS Chair, explained that the subcommittee's recommendation comes from heavily considered expert opinion submitted during the review. She clarified, on a personal note, that she believes within the HERC's purview to make decisions that are more heavily based on the evidence, even if that decision runs contrary to what the subcommittee has recommended.

Coffman remarked that expert opinion and commercial insurance standards coupled with DMAP's administrative rule allowing 100 test strips for 90 days may have been a factor in HTAS's recommendation.

Saha added VbBS looked at the evidence independently to arrive at their conclusion to offer a lower number of test strips. Dodson asserted that 50 test strips per 90 days is closer to what the evidence supported than the HTAS coverage guidance recommendation.

Public Testimony

Saha invited the audience members who indicated they wished to speak to the testimony table and asked each person to identify any potential conflicts of interest. He asked each person to keep their remarks to three minutes.

***Dr. Farahnaz Joarder** is an adult endocrinologist from OHSU and was the appointed ad hoc expert for the HTAS review of this topic. She states no conflicts of interest. Her recommendations were identified as a consensus among colleagues who are specialists in diabetes care.

- Blood glucose monitoring is considered a clinically meaningful tool to help with behavior change and glycemic control.
 - Supported by literature, though the optimal level of frequency has not been studied well.
 - The primary study referenced by the subcommittee cited lack of well-designed studies
- Decisions should be individualized based on the judgment of the provider
 - Avoid excessive restriction placed on the provider when additional testing is needed to not impede care
 - Once a week testing is not clinically significant and not relevant when testing is needed
- Actual cost of test strips
 - Recent Medicare guideline change reduces covered costs to \$22.40/month (down from \$77.90)
 - Cost reduction programs (such as Walmart's) offer strips at a significantly reduced cost within Medicare's guideline
 - Are there differences in the quality of meters and test strips that justify the cost differences? (Not answered)
- Allow patients treated with once-daily insulin injection to test more frequently to avoid instances of hypoglycemia that may be due to:
 - missed meals
 - increased activity

- accidentally administer more insulin
- Urge delay in implementation to allow:
 - study of impact of Medicare guideline decision
 - review of Patient Centered Outcome Research Institute (PCORI) study and Oregon cost evaluation called for by SB 169

The Chairman noted the PCORI results will not be available until 2016

Williams asked, short of not imposing limitations, what is a reasonable number? Dr. Joarder stated 100 test strips per 30/days is reasonable for most patients. Further she stated all patients who test derive some benefit whether guiding medication or behavioral changes.

Saha noted that it has become the standard to test daily, even multiple times a day, without evidence to support that frequency. There is a reluctance to pull back, to test less frequently and wait for the study results. He posed a question comparing testing frequency for patients on daily fixed doses of anti-coagulant medications (like Warfarin) with glucose testing for patients on a daily fixed dose of oral medication who have an HbA1c less than 8 percent (patients not requiring multiple daily injections of insulin). After the medication is titrated to the therapeutic dose, testing is decreased to every 2-4 weeks. What does weekly or daily testing add to the disease management?

Jorder stated the answer depends on what agents are given and feels it is important to know within a few days if changes are needed, rather than waiting every 3 months for a blood test. A single test is not meaningful. She looks for relative value, needing more data to make decisions.

Saha pointed out there is a provision in the coverage guidance allowing for more testing supplies when a patient is having new or unusual symptoms. The coverage guidance is meant to be limiting for patients who are stable.

***Paul Radensky, MD** is an internist by training and a health policy attorney with McDermott Will & Emery. He is also outside council to Abbott and Roche.

He submitted a study conducted by his organization attempting to update the trusted source report used by the Commission. He stated the submitted data is not firm or strong but urged the Commission not to simply state there is an absence of evidence, but to find specific evidence that supports the position the Commission is proposing.

- Urged the Commission to look at his submitted studies that seem to show 0.3-0.5 % changes in test results due to testing frequency
- All oral pharmacotherapy for diabetes treatment carries a warning label for risk of hypoglycemia
 - Cannot predict hypoglycemic events. Testing is needed.
- How will coverage guidance be operationalized?
 - Providers could be too frustrated with the process
- Medicare costs stated today by Commission members maybe be outdated.
 - Recent law changes discounting mail order supplies were applied to retail stores 7/1/13 (Medicare Advantage contracts are separate and not controlled by this law).

Coffman said he visited the CMS website within the past week and found information indicating the Medicare discounting did not apply to retail stores. Radensky urged anyone to call Jonathan Blum, CMS Deputy Administrator, for confirmation.

On the question of how the guidance should be implemented, Saha clarified the Commission's purview is to study and state the evidence. Other groups are charged with the hard work of implementation and, sometimes, choose not to when it is more administratively complex than is beneficial.

Saha, who works for the Veteran's Administration, the biggest healthcare organization in the country, limits test strips to 100/90 days for those on insulin and 50/90 days for those who are not. Patients with increasing symptoms can get an additional 50 strips as needed.

***BJ Cavnor**, Executive Director of One in Four Chronic Health spoke about:

- Importance of an educated and empowered patient in managing their health
 - Coverage guidance is inconsistent with industry standard
- Importance of reducing health costs
 - Avoid short-sided policies that seem to save money in the short term but end up costing more later in uncontrolled chronic disease management
 - Hospitalization: upwards of \$9,000/patient
- Dispel misinformation about
 - Test strip black market – asserts this is non-existent
 - Cost of test strips – closer to \$0.65/strip rather than \$1.00 asserted earlier

Coffman asserted that there are easily accessible websites offering cash for unused test strips found by a simple internet search. Mr. Cavnor argued in his 25 years as a patient advocate he has never heard of this black market.

Gibson asked if there is evidence to support the claim that cutting back on test strips is “penny wise-pound foolish.” Is there any proof that short term savings costs more in the long term. Cavnor argued patients will need additional interventions (insulin, hospitalization). Saha stated that linking test strips to hospitalization is flawed logic, there is no correlation.

***Laura Keller**, Advocacy Director, American Diabetes Association

- Referenced a submitted letter from Senator Jackie Winters, stating an opinion that placing limitations on test strips would limit Oregon's ability to provide improved diabetes care and prevent long-term complications
- ADA and endocrine societies released recent report about hypoglycemia and sulfonylurea medication
 - Requested to add sulfonylureas to the list of exceptions due to the significant risk of hypoglycemic episodes for anyone taking the medication, even if they have never had an episode previously
- Today's OHA presentation stated managing diabetes is a performance metric for the CCOs
 - To make changes in diabetes you have to have patients who are educated and have the tools they need
- There are studies to show what long-term complications are avoided by providing test strips
 - ADA has lobbied each state to add test strips to their health care plans
 - Health care exchanges have strips as a mandatory benefit

- Diabetes is costly; asserts that if strips didn't make a difference, those laws to add strips wouldn't have passed
- Want to prevent complications of diabetes (eye, renal, heart problems) before they are an issue
- Urged creating a clear and easy to use exceptions process
- HbA1c is not a good indicator of blood glucose, being an average of blood sugar over 3 months. A person who has an erratic blood sugar (high-highs and low-lows) might have a HbA1c in an acceptable range but have increased rates of complication.
 - It is not a useful tool to drive medication management
 - Urge to provide a minimum of 100 strips and not consider decreasing to 50
 - Health exchange is 100
 - Most in VA system get close to 100

***Michelle Grove**, ANP, The Portland Clinic, board certified in diabetes management

- "We are not talking about 'diabetics.' We are talking about people who have diabetes. There's a difference."
- Limiting test strips is akin to driving without a speedometer
- Testing makes a difference in the day-to-day lives of people who live with this chronic disease
- Older adults with type 2 are more affected by hypoglycemic episodes, resulting in increased hospitalizations
- ADA standard of care is to test blood sugar before driving to reduce risk of accidents due to hypoglycemia
 - Limiting test strips may lead to more motor vehicle accidents
- Anecdotally, her patients who test often do well

Saha clarified that absence of test strips doesn't cause hypoglycemia. Evidence suggests *over-testing* leads to more hypoglycemia, on balance. As a clinician, he sees patients over-test and skip meals or take extra insulin as a result of test strip abuse, *creating* wildly fluctuating blood sugars. He cautioned Commissioners to not ignore the potential harms of test strips.

Commissioners discussed next steps for this coverage guidance, debating whether consensus could be reached today or whether an additional meeting should be scheduled to continue discussing the topic. Croswell urged continued discussion at a future meeting, allowing members to carefully consider testimony they heard today.

Ahmann remarked there are many examples of accepted medical practices that were later shown to not be effective, and even harmful, including bone marrow transplants for breast cancer. Sometimes evidence flies in the face of what we *think* is the standard of care and it is a hard decision.

Williams asked for more discussion about the studies that lead to the coverage guidance. Testimony presented here today was largely anecdotal, involving practical day-to-day living with diabetes. We should take those factors into consideration along with the evidence.

Gibson agreed we should take time to get the policy right. Though it is not helpful to have new studies brought to the meeting, we should take time to see how they might affect our thinking.

Saha noted there is evidence of a small benefit to a certain amount of testing. To ensure we are not over-spending on a practice that does not do a lot of good, we need to establish limits. It is fair to mention that some of this guidance was reached through expert opinion and stakeholders input; it not clearly based on the evidence. In those areas, we included what *seemed* reasonable. He added it was fair to consider hypoglycemic control.

Saha asked if there was any evidence to support once per week testing. Little answered that one trial looked at different testing frequency. Testing once per week was compared to 3-7 times per week. No difference in HbA1c was found.

This topic was carried forward to the next HERC meeting. After hearing the public testimony today (coupled with all testimony presented over the formal coverage guidance comment period), the next meeting should focus on Commission discussion and deliberation.

Topic: Carotid Endarterectomy vs. Medical Management and Screening for Carotid Artery Stenosis

Evidence summary presented:

- Carotid endarterectomy in symptomatic patients
 - Highly beneficial for patients with $\geq 70\%$ stenosis without near occlusion
 - Some benefit for patients with 50% to 69% stenosis
 - No benefit for patients with 30% to 49% stenosis
 - Harms exceed benefit in patients with stenosis $< 30\%$
 - Uncertain benefit in patients with carotid near-occlusion
 - Results generalizable only to surgically-fit patients operated on by surgeons with low complication rates
- Carotid endarterectomy in asymptomatic patients
 - Benefit exceeds harms for patients with stenosis $> 60\%$ when performed in centers with complication rate of 3% or less
- Population screening for carotid stenosis
 - Benefit does not outweigh harms

For OHP implementation, VbBS adopted two guidelines based on the coverage guidance:

- Screening not covered for asymptomatic patients
- Carotid Endarterectomy covered according to criteria identified in the coverage guidance

Proposed coverage guidance:

HERC COVERAGE GUIDANCE

Carotid endarterectomy is recommended for coverage in patients with 70-99% carotid stenosis without near-occlusion (*strong recommendation*).

Carotid endarterectomy is not recommended for coverage for patients with less than 50% carotid stenosis (*strong recommendation*).

Coverage of screening for asymptomatic carotid artery stenosis in the general primary care population is not recommended (*strong recommendation*).

For patients with 50 – 69% carotid stenosis who are symptomatic (recent transient ischemic attack or ischemic stroke), carotid endarterectomy is recommended for coverage only for those who have failed optimal medical management (*weak recommendation*).

Saha remarked that the studies used for this coverage guidance are pretty old; statins were not commonplace during this timeframe. Improvements made since the studies were conducted may have led to improved surgical technique and better medical management.

Further, the reported benefit of surgery was very small, 4% vs. 3%. Though there were fewer patients having recurrent strokes in 4 years, those who did experienced it during surgery. Essentially, this is trading a 1% risk reduction of stroke over 4 years for a risk of immediate stroke. Medical management may have improved so much since the study was conducted that any surgical benefit is lost.

Saha mentioned a recent review by the Annals of Internal Medicine concluded that, for the asymptomatic patient, a recommendation could not be made because they could not be sure the control group during the study could reasonably be compared to a control of today's patients with this condition.

He also pointed out that the second clause of the proposed guidance, which recommends medical management for symptomatic patients, seemed flawed. Once a patient is symptomatic, waiting to do surgery decreases the benefit. Little clarified that medical management was not addressed in the evidence. Those discussions were part of the subcommittee deliberations.

Wiley suggested a change to that clause, to strike wording about optimal medical management:
For patients with 50 – 69% carotid stenosis who are symptomatic (recent transient ischemic attack or ischemic stroke), carotid endarterectomy is recommended for coverage only for those who have failed optimal medical management (weak recommendation).

The members discussed if the coverage guidance should address recommendations for asymptomatic patients (as the first clause for patients with 70-99% carotid stenosis does not specify the target population, thereby applying to asymptomatic as well as symptomatic patients).

Saha was concerned that the evidence presented only evaluates relative risks. He asserted we should be looking at absolute risks. Little verified the Cochrane review does not address absolute risks. He asked Little to look at a newer systematic review that was not considered for this coverage guidance proposal. The findings can be presented to HERC rather than going back to HTAS.

Evidence-based Guidelines Subcommittee (EbGS) Report
[Meeting materials, pages 205-249](#)

Due to time constraints the EbGS report was carried forward to the next meeting.

Coverage Guidance Development Process
[Meeting materials, page 250](#)

Coffman presented an updated algorithm, adding an additional pathway for the evaluation of treatments of unknown risk compared to alternative treatments.

MOTION: To accept the amended algorithm as presented. Carries: 11-0.

Next Meeting Discussion

Commissioners agreed that an additional meeting should be scheduled and concluded that the best member attendance could be achieved with a meeting date in the afternoon of Thursday, December 5, 2013.

Public Comment on Topics Not Listed on the Agenda

There was no additional public comment at this time.

Adjournment

Meeting was adjourned at 4:40 pm. Next meeting will be from 2:00-5:00 pm on Thursday, December 5, 2013 at the Meridian Park Hospital Health Education Center in Conf. Room 117 B&C.

Section 2.0

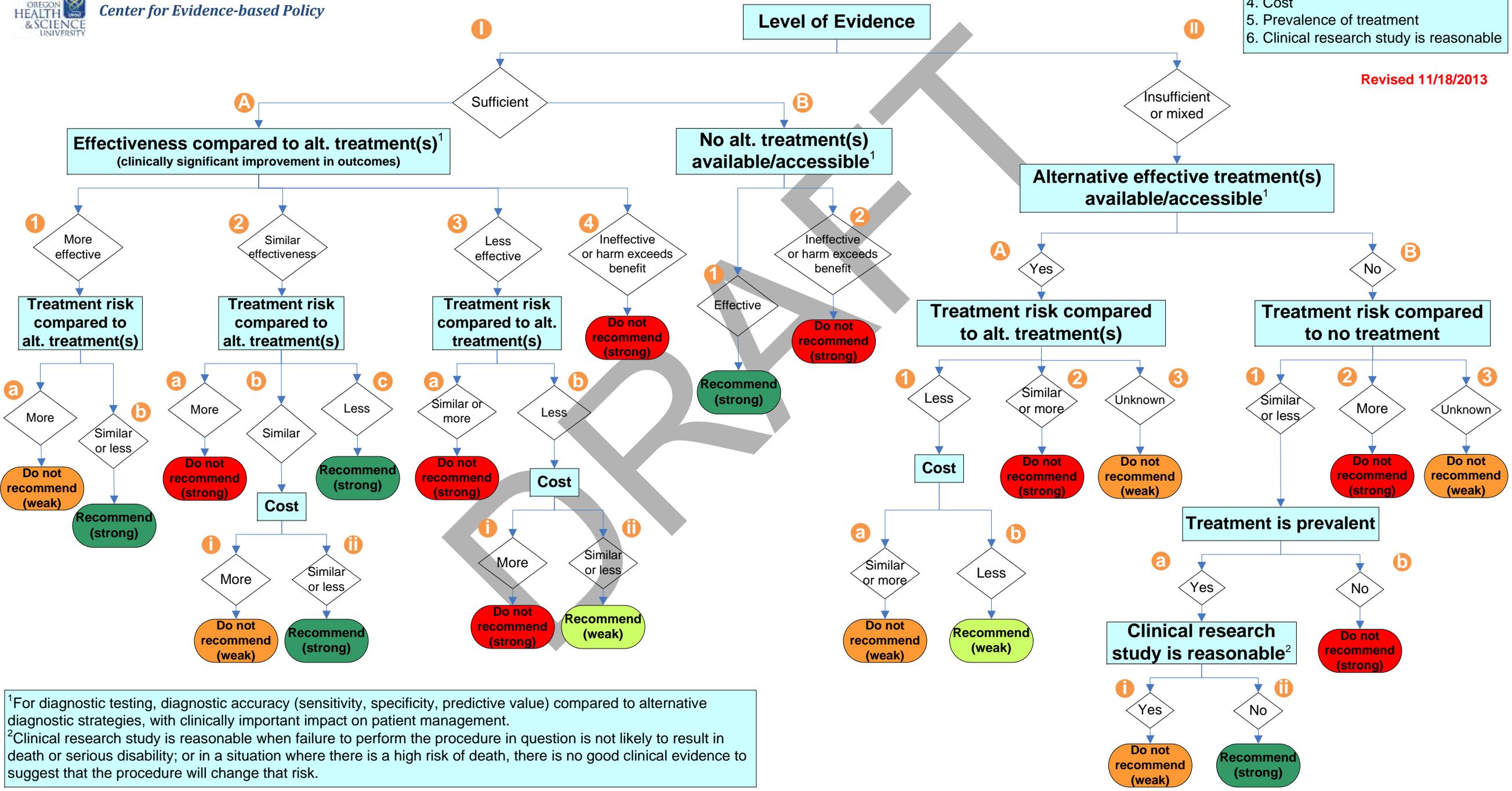
Staff Report

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

Revised 11/18/2013



¹For diagnostic testing, diagnostic accuracy (sensitivity, specificity, predictive value) compared to alternative diagnostic strategies, with clinically important impact on patient management.
²Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Section 3.0

Coverage Guidances-HTAS

Self-Monitoring of Blood Glucose Coverage Guidance Proposal

Self-Monitoring of Blood Glucose Coverage Guidance Language as proposed 10/10/13:

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*¹).

Supplies for self-monitoring of blood glucose, up to 100 test strips for 90 days, is recommended for coverage for the following patients with type 2 diabetes not requiring multiple daily insulin injections (*weak recommendation*²):

- Patients newly diagnosed and receiving diabetes education
- Patients changing treatment regimens
- Patients with unexplained or new onset hyperglycemia
- Patients with recent history of hypoglycemia
- Patients with comorbid conditions affecting diabetic control
- Patients with microvascular or macrovascular complications of diabetes
- Patients on basal (once daily) insulin
- Patients on systemic corticosteroid therapy

For other patients with type 2 diabetes mellitus not requiring insulin, home blood glucose monitors and related diabetic supplies are recommended for coverage 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*).

Note: This guidance does not apply to pregnant women.

Decision points

- 1) **Should the number of test strips for certain conditions be 100 or 50?**
- 2) **Should the list of conditions for which additional strips are covered be changed, or be left as is?**
 - a. **Consider adding sulfonyureas**
 - b. **Consider modifying comorbid conditions (or splitting into acute and chronic with differential numbers of strips)**
- 3) **Should a simpler guidance be adopted? (Alternative B)**

¹ 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.

² 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.

Self-Monitoring of Blood Glucose Coverage Guidance Proposal

ALTERNATIVE LANGUAGE

Alternative A (Discuss each point in blue):

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*).

Supplies for self-monitoring of blood glucose, up to 50/100 test strips for 90 days, is recommended for coverage for the following patients with type 2 diabetes not requiring multiple daily insulin injections (*weak recommendation*):

- Patients newly diagnosed and receiving diabetes education
- Patients changing treatment regimens
- Patients with unexplained or new onset hyperglycemia
- Patients with recent history of hypoglycemia
- [Patients with chronic comorbid conditions affecting diabetic control \(e.g. bulimia\)](#)
- Patients with microvascular or macrovascular complications of diabetes
- Patients on basal (once daily) insulin
- Patients on systemic corticosteroid therapy

Supplies for self-monitoring of blood glucose, up to 25 test strips for 180 days, is recommended for coverage for the following patients with type 2 diabetes not requiring multiple daily insulin injections (*weak recommendation*):

- Patients who have initial HbA1c levels greater than 8.0%
- [Patients on sulfonylureas](#)
- [Patients with acute comorbid conditions affecting diabetic control \(e.g. gastroenteritis resulting in dehydration, prolonged NPO status\)](#)

All diabetic patients should have a structured education and feedback program for self-monitoring of blood glucose (*strong recommendation*).

Self-Monitoring of Blood Glucose Coverage Guidance Proposal

Alternative B:

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*).

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

All diabetic patients should have a structured education and feedback program for self-monitoring of blood glucose (*strong recommendation*).

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

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

DRAFT for HERC Meeting Materials 12/5/2013 (as approved by HTAS)

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*).

Additional supplies for self-monitoring of blood glucose, up to 100 test strips for 90 days, is recommended for coverage for the following patients with Type 2 diabetes (*weak recommendation*):

- Patients newly diagnosed and receiving diabetes education
- Patients changing treatment regimens
- Patients with unexplained or new onset hyperglycemia
- Patients with recent history of hypoglycemia
- Patients with comorbid conditions affecting diabetic control
- Patients with microvascular or macrovascular complications of diabetes
- Patients on basal (once daily) insulin
- Patients on systemic corticosteroid therapy

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. 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.

DRAFT

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

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.

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

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

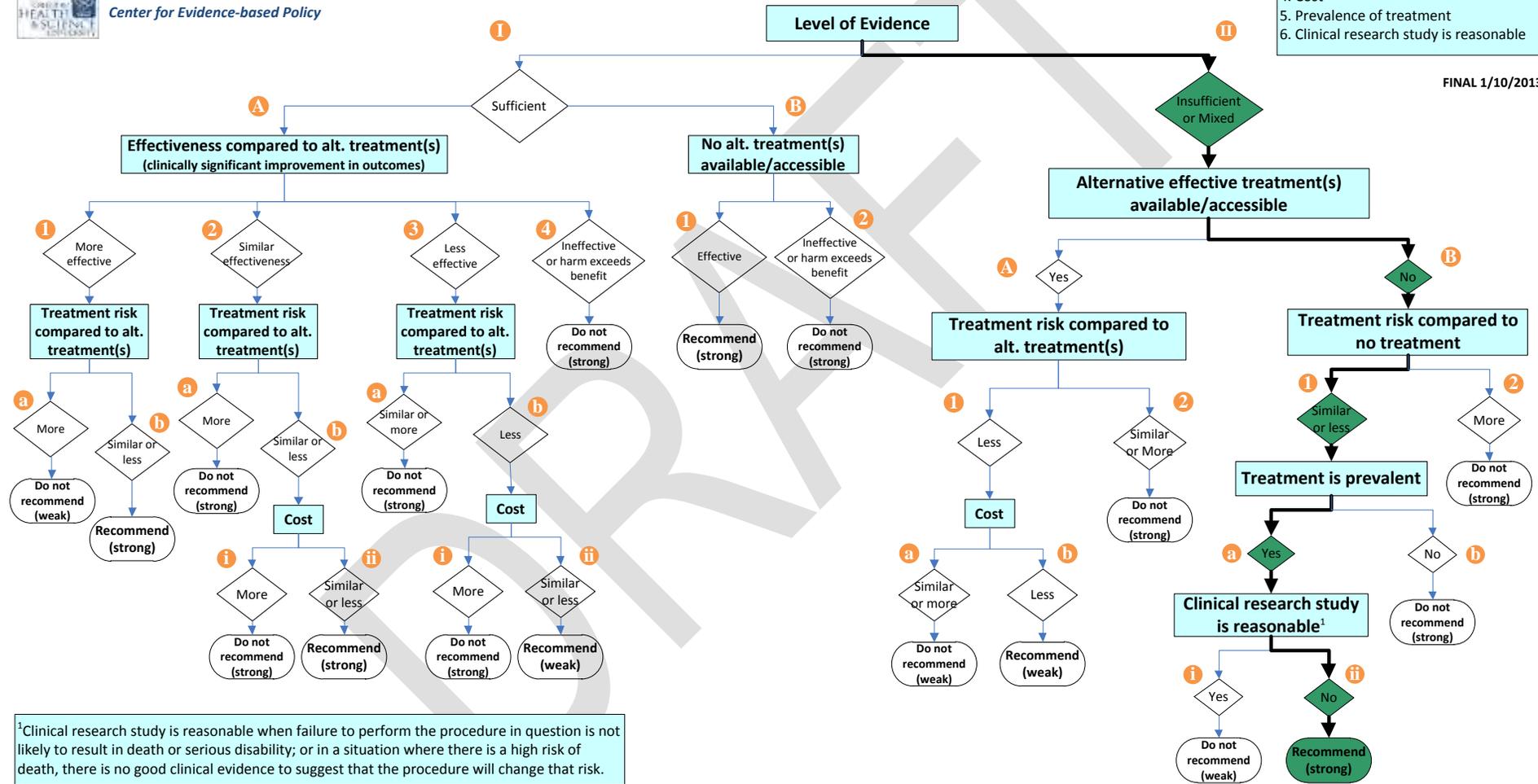


HERC Guidance Development Framework

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%

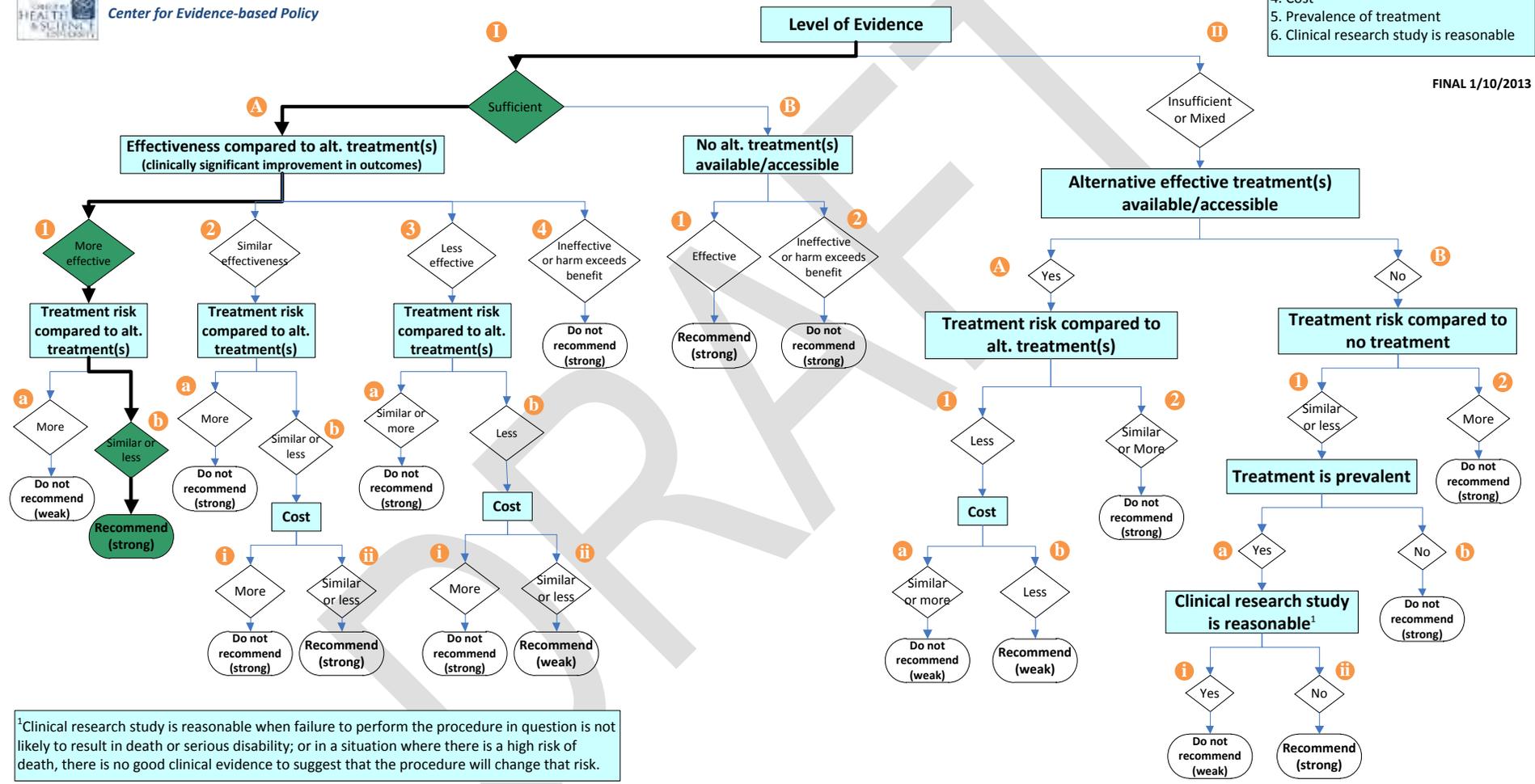


HERC Guidance Development Framework

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

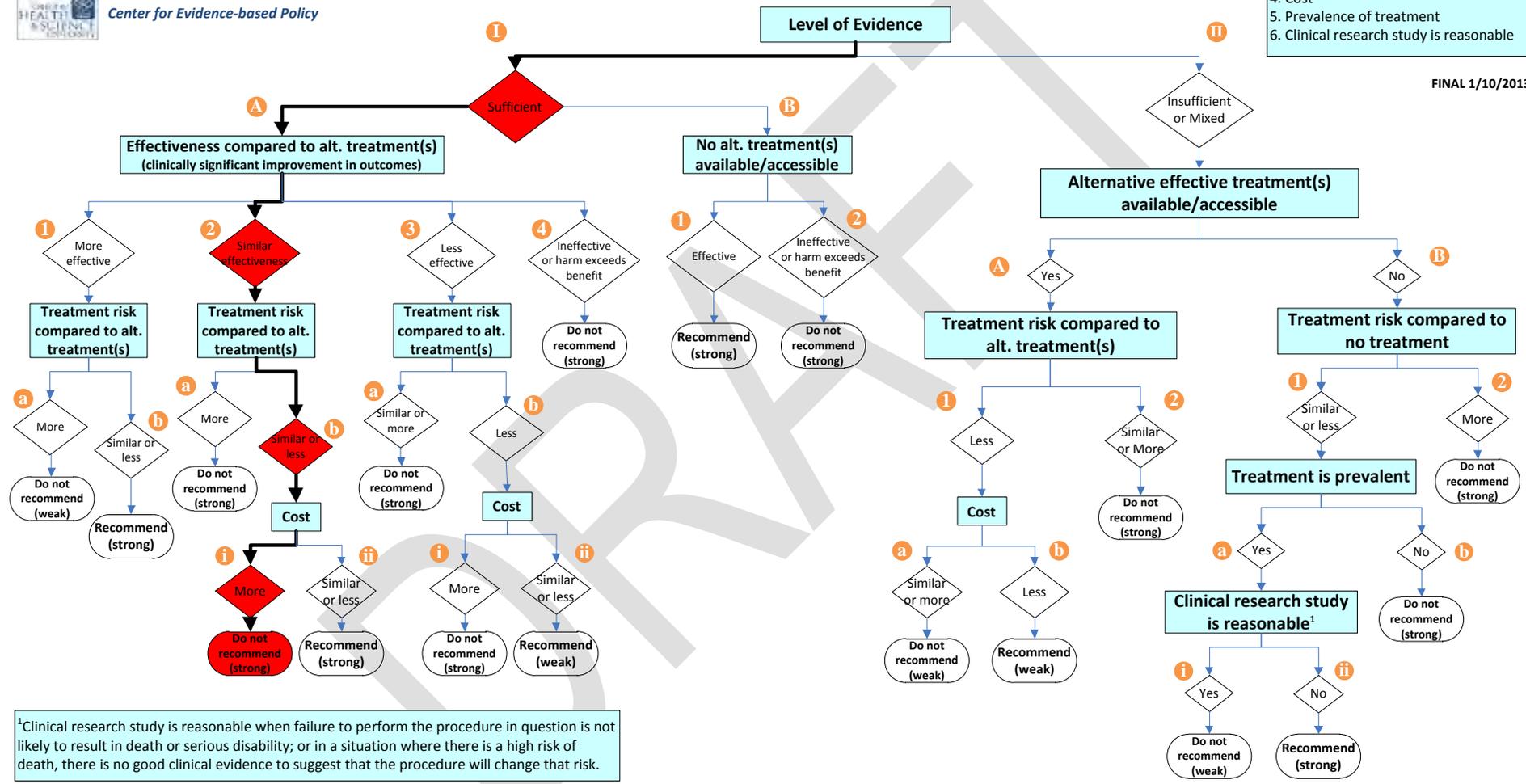


HERC Guidance Development Framework

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



CG-Self Monitoring of blood glucose

Question: How should the Coverage Guidance - Self Monitoring of Blood Glucose - be applied to the Prioritized List?

Question source: Health Technology Assessment Subcommittee

Coverage Guidance Recommendation:

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*).

Additional supplies for self-monitoring of blood glucose, up to 100 test strips for 90 days, should be covered for the following patients with Type 2 diabetes (*weak recommendation*):

- Patients newly diagnosed and receiving diabetes education
- Patients changing treatment regimens
- Patients with unexplained or new onset hyperglycemia
- Patients with recent history of hypoglycemia
- Patients with comorbid conditions affecting diabetic control
- Patients with microvascular or macrovascular complications of diabetes
- Patients on basal (once daily) insulin
- Patients on systemic corticosteroid therapy

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.

Current Prioritized List Status:

Line: 10

Condition: TYPE I DIABETES MELLITUS (See Guideline Notes 1,64,65,76)

Treatment: MEDICAL THERAPY

ICD-9: 250.01,250.03,250.11,250.13,250.21,250.23,250.31,250.33,250.51,250.53,250.61,250.63,250.71,250.73,250.91,250.93,251.3,V53.91,V65.46

CPT: 49435,49436,90935-90947,90989-90997,92002-92014,92227,95250,95251,96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,99487-99496,99605-99607

HCPCS: G0108,G0245,G0246,G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274,S9145,S9353

CG-Self Monitoring of blood glucose

Line: 33
Condition: TYPE II DIABETES MELLITUS (See Coding Specification Below) (See Guideline Notes 1,7,8,64,65,76)
Treatment: MEDICAL THERAPY, BARIATRIC SURGERY WITH BMI >= 35
ICD-9: 250.00,250.02,250.10,250.12,250.20,250.22,250.30,250.32,250.40,250.42,250.50,250.52,250.60,250.62,250.70,250.72,250.80,250.82,250.90,250.92,V53.51
CPT: 43644,43645,43770-43775,43846-43848,90935-90947,90989-90997,92002-92014,92227,96150-96154,97802-97804,98966-98969,99051,99060,99070,99078,99201-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,99487-99496,99605-99607
HCPCS: G0108,G0245,G0246,G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274,S2083,S9145,S9353,S9537

CPT codes 43644-43645 and 43846-43848 (Roux-En-Y gastric bypass) and 43770-43775 (laparoscopic adjustable gastric banding) are only included on this line as treatment according to the requirements in Guideline Note 8 when paired with:
1) a primary diagnosis of 250.x0 or 250.x2 (Type II Diabetes with or without complication);
2) a secondary diagnosis of 278.00 (Obesity, Unspecified) or 278.01 (Morbid Obesity); AND,
3) a tertiary diagnosis code of V85.35-V85.45 (BMI >= 35).

HERC Staff Assessment

After discussions with DMAP, there are some implementation issues with adoption of the coverage guidance box verbatim. ICD-9 does not allow distinguishing based on a1c level, rather it only has “controlled” and uncontrolled”. Based on this, defining uncontrolled for the purposes of determining which icd-9 codes fall under the guideline note is important.

The maximum number of test strips any study used in these populations was 12 strips in 30 days.

There are currently some codes located on lines 1, 10, and 33 to support diabetic self-management, but many are not currently on the Prioritized List. Historically, there were concerns about reimbursement through the FQHC model, however, alternative payment methodologies are being developed that allow for options for things like group visits.

HERC Staff Recommendations:

1) Add a new guideline, based on Alternative A or B

Alternative A based guideline

ANCILLARY GUIDELINE XX SELF-MONITORING OF BLOOD GLUCOSE IN TYPE 2 DIABETES

LINE 33

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 covered.

A structured education and feedback program for self-monitoring of blood glucose is required.

CG-Self Monitoring of blood glucose

Supplies for self-monitoring of blood glucose, up to [50/100](#) test strips for 90 days, is recommended for coverage for the following patients with type 2 diabetes not requiring multiple daily insulin injections (*weak recommendation*):

- Patients newly diagnosed and receiving diabetes education
- Patients changing treatment regimens
- Patients with unexplained or new onset hyperglycemia
- Patients with recent history of hypoglycemia
- [Patients with chronic comorbid conditions affecting diabetic control \(e.g. bulimia\)](#)
- Patients with microvascular or macrovascular complications of diabetes
- Patients on basal (once daily) insulin
- Patients on systemic corticosteroid therapy

Supplies for self-monitoring of blood glucose, up to [25](#) test strips for [180](#) days, is recommended for coverage for the following patients with type 2 diabetes not requiring multiple daily insulin injections (*weak recommendation*):

- Uncontrolled diabetics (defined as HbA1c levels greater than 8.0%)
- [Patients on sulfonylureas](#)
- [Patients with acute comorbid conditions affecting diabetic control \(e.g. gastroenteritis resulting in dehydration, prolonged NPO status\)](#)

All diabetic patients should have a structured education and feedback program for self-monitoring of blood glucose (*strong recommendation*).

Alternative B based guideline

ANCILLARY GUIDELINE XX SELF-MONITORING OF BLOOD GLUCOSE IN TYPE 2 DIABETES

LINE 33

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 covered.

For patients with type 2 diabetes not requiring multiple daily insulin injections, supplies for self-monitoring of blood glucose, including up to 50 test strips for 90 days, is covered at the time of diagnosis and for those who require diabetic medication that may result in hypoglycemia.

If there is an acute change in glycemic control or active medication adjustment, an additional 50 strips are covered.

A structured education and feedback program for self-monitoring of blood glucose is required.

CG-Self Monitoring of blood glucose

2) Code placement recommendations

Code	Description	Current Placement	Staff Recommendation
97802	Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes	On Lines 1,10, 33 and 20+ other lines. Only open to dieticians	No change
97803	Medical nutrition therapy; re-assessment and intervention, individual, face-to-face with the patient, each 15 minutes	On Lines 1,10, 33 and 20+ other lines. Only open to dieticians	No change
97804	Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes	On Lines 1,10, 33 and 20+ other lines. Only open to dieticians	No change
98960	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; individual patient	DMAP Excluded File	Lines 1, 10, 33 This is currently a quality measure
98961	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; 2-4 patients	DMAP Excluded File	Lines 1, 10, 33
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; 5-8 patients	DMAP Excluded File	Lines 1, 10, 33
99078	Physician educational services rendered to patients in a group setting (eg, prenatal, obesity, or diabetic instructions)	500+lines	No change
HCPCS Level II Codes			
A4233-6	Batteries for home blood glucose monitors	DMAP Ancillary File	No change
A4253	Blood Glucose test strips, box of 50	DMAP Ancillary File	No change
A4255	Platforms for home blood glucose monitor, 50/box	DMAP Ancillary File	No change
A4256	Calibrator solutions/chips	DMAP Ancillary File	No change
A4258	Spring-powered device for lancet, each	DMAP Ancillary File	No change
A4259	Lancets, per box of 100	DMAP Ancillary File	No change
E0607	Blood glucose monitor	DMAP Ancillary File	No change
E2100	Blood glucose monitor with voice synthesizer	DMAP Ancillary File	No change
E2101	Blood glucose monitor with integrated lancet	DMAP Ancillary File	No change

CG-Self Monitoring of blood glucose

G0108	Diabetes outpatient self-management training services, individual, per 30 minutes	Lines 1,10,33	No change
G0109	Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes	DMAP Excluded File	Lines 1, 10, 33
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)	DMAP Ancillary Codes File. Not open.	Map to same lines as 97802- 97804 Is a quality measure
S9140	Diabetic management program, follow-up visit to non-MD provider	DMAP Ancillary File. Not covered by Medicare, used by BCBS for reporting purposes. Commercial payors using.	Lines 1, 10, 33
S9141	Diabetic management program, follow-up visit to MD provider	same	Lines 1, 10, 33

Specific Questions Pertaining to Self-Monitoring of Blood Glucose

Staff responses to questions raised after the October 10 HERC meeting.

1. Should patients on single daily insulin injections be separated from those on multiple daily injections (or should all patients on insulin be lumped together)? Do we have evidence that once-a-day insulin is more similar to being on oral agents than being on multiple injections? Does it include patients with once daily insulin being dose-adjusted, because most patients do not stay on a single dose of insulin over time?

The reason the evidence was presented this way was because the Clar SR included some studies that included patients on basal insulin. Of the 26 included RCTs, 7 included some patients using insulin and 3 did not specify what treatment patients received. While the details of the insulin regimen weren't specified in the SR, it excluded patients on "complex insulin regimens", therefore, the assumption is that they were limited to basal insulin.

The decision to not limit SMBG supplies in patients with Type 1 DM or those using multiple daily injections was not made based on evidence, but due to the practicalities of managing the disease. No evidence was identified for this group of patients. Given that there is evidence for patients on basal insulin, it would seem reasonable to include them in the coverage restrictions, or at least treat them the same as patients taking other potentially hypoglycemia-inducing medications (sulfonylureas).

The Malanda SR included only patients not using insulin and found similar results as Clar.

2. 50 vs. 100 strips per 90 days

100 strips/90 days is the current Medicare allowance for Type II DM, and is mirrored by many other payers. There is no evidence to support this testing frequency. The Veteran's Administration recommends 50 strips per 150 days for patients on oral medications, with extra strips accessible for patients in circumstances requiring closer monitoring or dose adjustments. There was only one study in the Clar review that compared more to less frequent testing. Scherbaum 2008 (N=202) compared low frequency SMBG (1X/week plus additional if suspected hypo or severe hyperglycemia) with high frequency SMBG (4X/week plus additional as above). This study demonstrated non-inferiority of less frequent testing (HbA1c in the low group = 6.9 vs. 7.1 in the high group, $p=0.002$), as well as no difference in healthcare utilization or changes in diabetes treatment.

Specific Questions Pertaining to Self-Monitoring of Blood Glucose

Public comment cited three additional studies for consideration. Of these, the highest frequency of SMBG in any of them was an average of 12 strips/month (Franciosi 2011; intervention group also had intensive nurse case management). The other study that specified strip usage was Polonsky 2011. The intervention in this study utilized a 7 point glucose profile (fasting, preprandial, 2 hour post prandial, bedtime) for three days (total of 21 strips) before each clinician visit, which occurred every three months. This results in an average of 9 strips/month.

An additional study was provided to the HERC at the last meeting (Harashima 2013). This study directed patients in the SMBG group to test an average of 23X/month, however, patients actually tested more than twice a day, for unclear reasons. Also of note is that this study was conducted in Japan, where the authors state “SMBG is not broadly applied in non-insulin treated T2D because it is not covered by health insurance”.

3. Rationale for 1 strip per week. Just because 1 was equivalent to 7 per week doesn't mean it makes sense – the clinical question of what the purpose is of 1 strip per week seems valid. We need to have a solid foundation of evidence indicating that 1 strip per week improves diabetes care before issuing a policy that doesn't make a lot of clinical sense. We need to scrutinize the 1 per week analysis carefully.

When analyzing those RCTs that found a statistically significant effect of SMBG, testing frequency ranged from only when not feeling well or after exercise, to 14 times a week (7 times a day, 2 days per week). While 1 time per week may not make sense clinically, it would be sufficient to test intermittently for hypoglycemia, or could be used to complete a four point profile monthly, or a seven point profile every other month. Some other amount that might make more sense clinically could certainly be considered, but the evidence is not helpful on this question.

4. Should we base our guidance on evidence of effectiveness of SMBG without education, or with? Even if the reality is that most patients won't get education, do we deprive those who could get SMBG + education the clinical benefit of that combination? In the trials of SMBG + education, how many strips were used?

Of the 7 RCTs that included education and feedback, testing frequency was as follows:

- Unspecified (3 RCTs)

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- 3x/day, 2 days/week (24/mo)
- 4X/day, 2 days/week (32/mo)
- 1-3X/day, 3 days/week (max 36/mo)
- 6X/day, 2 days/week (48/mo)

5. Does the evidence tell us anything about the value of strips for detection/documentation of hypoglycemic episodes, or just for improvements in glycemic control? There is clear, common-sense value in having strips for detecting hypoglycemia. It might be that having a few strips on hand is adequate, but then it shouldn't be framed as one strip a week, it should be X strips per month. Also, having strips for hypoglycemic episodes might be most important in those who are more well-controlled, particularly on sulfonylureas, who currently get no strips.

Six RCTs in the Clar review reported on hypoglycemic events, with results being inconsistent. However, the authors report a “suggestion that occurrence of hypoglycemia was increased with more frequent self-monitoring”. The details of those 6 studies are presented below:

Author Year	N / length of study/ Quality	Intervention	Control	Outcomes (pertaining to hypoglycemia)
Barnett 2008	610 / 27 wks/ high	Instructed on SMBG, tested 7x/day, 2 days/wk, diet and lifestyle instruction, oral meds	Same as intervention except no SMBG	8.7% of SMBG group had HE (total of 51: 27 symptomatic, 11 asymptomatic, 11 SMBG-confirmed, 2 non-graded); 7.0% of control had HE (total of 66: 64 symptomatic, 2 non-graded) – no stat testing done No severe hypoglycemia
Farmer 2007	453 / 12 mos/ high	SMBG less intensive: test 3x/day, 2 days/wk SMBG intensive:	Usual care, no SMBG	1 or more grade 2 HE in 14 control pts, 33 less intensive pts, 43 more

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		same as less intensive, plus education, interpretation		intensive pts (p<0.001)
Guerci 2003	689/ 24 wks/ moderate/poor	SMBG ≥ 6x/wk, education only with MD visit Q 6 wks, HbA1c every 12 wks	Same as intervention except no SMBG	more HE in SMBG group (10.4% vs. 5.2%, p=0.003)
Kibriya 1999	64/ 18 mos/ poor	SMBG 2-3x/day, every 2 wks, education	Education, monthly doctor visits	fewer HE with SMBG (0.172 vs. 0.354 per patient-year, p=0.03)
O’Kane 2008	184/ 1 year/ high	SMBG: 4 fasting and 4 PP tests/week, with instruction, plus education, doctor visits Q 3 months	No SMBG, otherwise same as intervention	No difference in HE, but study not powered to detect one (per Clar)
Scherbaum 2008	202/ 12 mos/ high	High SMBG: 4x/wk + add’l if suspected hyper/oglycemia	Low SMBG: 1x/wk + add’l if suspected hyper/oglycemia	Increased HE in the High group (1 or several), stat sig for 1 HE (p=0.02)

HE = hypoglycemic episode

Pertinent text from studies detailed in table above

Barnett 2008

From Methods:

Instruction included information on how to use the glucose metre, how to check it was working, when to take measurements, how to record them in the patient diary and what to do in the event of asymptomatic hypoglycaemia (measured glucose <3 mmol/l on SMBG without symptoms/signs suggestive of hypoglycaemia) or SMBG-confirmed hypoglycaemia. Both SMBG and non-SMBG patients were required to keep a patient diary to record any symptoms suggestive of hypoglycaemia including information about their last meal, temporal association to antidiabetic agent therapy and actions taken, e.g. resolved after eating and third party assistance required. All patients were provided with information on symptoms, avoidance and management of hypoglycaemia with their patient diary. In the event of suspected hypoglycaemia, subjects in the SMBG group

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were instructed to take a blood glucose reading and to follow the instructions on management of hypoglycaemia in the patient diary. For patients in the SMBG group, the patient diary also provided a record of the SMBG results.

Farmer 2007

From Methods:

Episodes of hypoglycaemia were categorised as grade 2 (mild symptoms requiring minor intervention), grade 3 (moderate symptoms requiring immediate third party intervention), or grade 4 (unconscious).

From Results:

During the trial one or more grade 2 hypoglycaemic episodes were experienced by 14 patients in the control group, 33 in the less intensive intervention group, and 43 in the more intensive intervention group ($\chi^2_2=18.3$, $P<0.001$). Only one patient in the control group experienced a grade 3 hypoglycaemic episode.

From Discussion:

The increased recording of hypoglycaemia in the self monitoring arms may be a result of an increased awareness of low blood glucose levels from using the meter rather than a true biochemical difference between groups.

Guerci 2003

From Results:

In all, 78 patients reported at least one episode of hypoglycemia (symptomatic or asymptomatic) during the study; 53 (10.4%) patients in the SMBG group and 25 (5.2%) patients in traditional assessment group. These proportions were statistically different ($P = 0.003$) due to the difference between groups solely for asymptomatic hypoglycemia ($P = 0.001$). No serious episode of hypoglycemia was reported during this study.

Kibriya 1999 (conducted in Bangladesh, included only patients who were "higher-middle class to rich")

From Results:

During 18 months of follow-up ten patients from Gr-I [no SMBG] had a total of 17 episodes of hypoglycaemic symptoms and 5 patients from Gr-II had seven similar episodes. Hypoglycaemic episodes per patient year follow-up were significantly higher among Gr-I patients (0.354 vs. 0.172, $P= 0.03$).

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O'Kane

From Results:

There were no differences between groups in the incidence of reported hypoglycaemia at any time points.

Scherbaum 2008

From Methods:

Patients were randomly assigned to two strategies of SMBG. Low group: SMBG with one measurement a week and additional measurement in the event of suspected hypoglycaemia or severe hyperglycaemia or high group: four measurements a week on Tuesdays, Thursdays and one day of the weekend before dinner and one additional measurement before lunch, and also additional measurement in the event of suspected hypoglycaemia or severe hyperglycaemia. Hypoglycaemia was defined as an SMBG, 3.2 mMol/L (60 mg/dl). Severe hypoglycaemia was defined as any hypoglycaemia with the need for assistance by another person.

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From Results:

The number and type of SAE and AE was similar between the groups except for hypoglycaemia, which was increased in the high group (Table 4). No hypoglycaemic shock or hyperosmolar coma occurred.

Relevant hypoglycemia	Low Frequency SMBG	High Frequency SMBG	P value
One event	1/100 (1%)	9/102 (9%)	0.02
Several events	4/100 (4%)	9/102 (9%)	0.25

From Discussion:

No differences were observed with respect to AE's and SAE's, except for hypoglycaemia, which occurred more often in the high group probably due to the higher frequency of measurements.

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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	<p>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.</p> <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). <ol style="list-style-type: none"> a. The AADE 7 are as follows: <ol style="list-style-type: none"> 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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Stakeholder	#	Comment	Disposition
		<ul style="list-style-type: none"> 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	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 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.	Thank you for this summary of the Clar review.
	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 c. Did the patients get the impression that SMBG was good? <p>How does benefit vary by starting HbA1c, frequency, education, susceptibility to hypoglycemia, treatment, age,</p>	See comment #6

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Stakeholder	#	Comment	Disposition
		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-counterpoint 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). 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: “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

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			targets, postprandial SMBG may be appropriate. (E) (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	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	<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 	Thank you for your input.

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Stakeholder	#	Comment	Disposition
		<p>Current Role of Self-Monitoring of Blood Glucose in Non-Insulin Treated Type 2 Diabetes, J Diabetes 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, Diabetes Care 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, Cochrane Database Syst Rev, 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. Diabetes Care 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. Diabet. Med. 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. J Diabetes. 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. Diabetes Care 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. Am J Manag Care 2008; 14:131-140</p> <p>(11) American Diabetes Association, Economic Costs of Diabetes in U.S. in 2012, Diabetes Care 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, Diabetes Educator 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, Diabetes Care 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, Diabetes Care 2012; 35:2100-2107.</p>	

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

Stakeholder	#	Comment	Disposition
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>	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. Another Cochrane review (Malanda 2012) was identified by the expert for this topic. It included only Type 2 diabetics not on insulin and had similar findings. HTAS elected to allow up to 100 test strips per 90 days for patients on basal insulin.
	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. HTAS elected to allow up to 100 test strips per 90 days for patients with a recent history of hypoglycemia.
	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: 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. 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. 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 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. 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</p>	<p>HTAS elected to allow up to 100 test strips per 90 days for patients changing treatment regimens, those with comorbid conditions affecting diabetic control and those on systemic corticosteroid therapy.</p>

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		study. 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 hose 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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		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>HTAS elected to allow up to 100 test strips per 90 days for patients newly diagnosed, changing treatment regimens, with a history of hypoglycemia, and with comorbid conditions affecting diabetic control.</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%; text-align: center; border-collapse: collapse;"> <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> 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. 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. References 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>

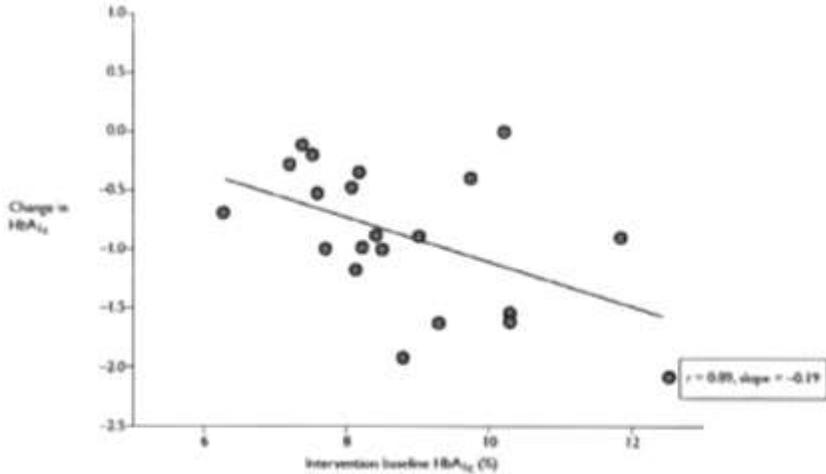
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		<p>Supplement 1 (January 2011): S11 - S61.</p> <p>2 AACE Diabetes Mellitus Clinical Practice Guidelines Task Force. "American Association of Clinical Endocrinologists Medical Guidelines for Developing a Diabetes Mellitus Comprehensive Care Plan." <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.
	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>	<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]</p>
	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 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</p>	<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%.</p>

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		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%.	HTAS elected to allow a number of exceptions to this limitation.
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.
	65	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	The Clar review concluded that SMBG in T2DM is not cost-effective.

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

Stakeholder	#	Comment	Disposition																																																						
		<p>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>Estimated Data for Oregon - Percentage of Adults with Diagnosed Diabetes (1994-2010)</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>4.3</td></tr> <tr><td>1997</td><td>4.8</td><td>4.6</td></tr> <tr><td>1998</td><td>5.0</td><td>4.8</td></tr> <tr><td>1999</td><td>5.3</td><td>5.1</td></tr> <tr><td>2000</td><td>5.5</td><td>5.3</td></tr> <tr><td>2001</td><td>5.8</td><td>5.6</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	4.3	1997	4.8	4.6	1998	5.0	4.8	1999	5.3	5.1	2000	5.5	5.3	2001	5.8	5.6	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	
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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 controlled, non-insulin patients with Type 2 diabetes, study participants utilized SMBG twice per week on average.</p>	See comment #12																																																						

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

Stakeholder	#	Comment	Disposition
	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 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	Neither of these studies address the value of SMBG over no SMBG. See comment #12.

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

Stakeholder	#	Comment	Disposition
		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.	
	73	<p>Any HbA1c Targets Should be Consistent With Professional Guidelines</p> <p>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.</p> <p>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%.</p>	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	<p>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.</p> <p>References:</p> <p>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.</p> <p>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</p> <p>3 Klonoff DC, et al. Consensus Report: The current role of self-monitoring of blood glucose in non-insulin-treated Type 2 diabetes. J Diabetes Sci Technol. 2011;5(6):1529-1548.</p> <p>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. Diabet Med. 2005;22:900 –906, 2005.</p> <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</p>	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>controlled, noninsulin-treated Type 2 diabetes: results from the Structured Testing Program study. Diabetes Care. 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. J Diabetes Sci Technol. 2011: 5(6):1529-1548.</p> <p>7 Ibid Klonoff DC, et al. J Diabetes Sci Technol. 2011: 5:1529-1548.</p> <p>8 Polensky WH, Fisher L. Self-monitoring of blood glucose in noninsulin-using type 2 diabetic patients. Diabetes Care. 2013;36:179-182.</p> <p>9 American Diabetes Association. Diabetes Care. 2011;34(Suppl 1):S11-S61. Handelsman Y, et al. Endocr Pract. 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>	

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: CAROTID ENDARTERECTOMY VS. MEDICAL MANAGEMENT AND SCREENING FOR CAROTID ARTERY STENOSIS

DRAFT for HERC meeting materials 12/5/2013

HERC COVERAGE GUIDANCE

Carotid endarterectomy is recommended for coverage ~~in-for~~ patients who are symptomatic (recent transient ischemic attack or ischemic stroke) and who have ~~with~~ 70-99% carotid stenosis without near-occlusion (*strong recommendation*).

For patients with 50 – 69% carotid stenosis who are symptomatic despite optimal medical management, carotid endarterectomy is recommended for coverage (*weak recommendation*).

Carotid endarterectomy is not recommended for coverage for symptomatic patients with less than 50% carotid stenosis (*strong recommendation*).

Carotid endarterectomy is recommended for coverage for patients with asymptomatic carotid stenosis of at least 60% only for those who do not tolerate (or have contraindications to) best current medical therapy (*weak recommendation*).

~~Coverage of s~~Screening for asymptomatic carotid artery stenosis in the general primary care population is not recommended (*strong recommendation*).

~~For patients with 50—69% carotid stenosis who are symptomatic (recent transient ischemic attack or ischemic stroke), carotid endarterectomy is recommended for coverage only for those who have failed optimal medical management~~ (*weak recommendation*).

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

Chambers B.R., & Donnan, G. (2005). Carotid endarterectomy for asymptomatic carotid stenosis. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD001923. DOI: 10.1002/14651858.CD001923.pub2. Retrieved July 23, 2012, from <http://summaries.cochrane.org/CD001923/carotid-endarterectomy-for-asymptomatic-carotid-stenosis>

Publication status and date: Edited (no change to conclusions), published in Issue 4, 2008.

Grant, E.G., Benson, C.B., Moneta, G.L., Alexandrov, A.V., Baker, J.D., Bluth, E.I., et al. (2003). Carotid artery stenosis: Gray-scale and Doppler US diagnosis – Society of Radiologists in Ultrasound Consensus Conference. *Radiology*, 229(2), 340-346.

Rerkasem, K., & Rothwell, P.M. (2011). Carotid endarterectomy for symptomatic carotid stenosis. *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD001081. DOI: 10.1002/14651858.CD001081.pub2. Retrieved July 23, 2012, from <http://summaries.cochrane.org/CD001081/carotid-endarterectomy-for-symptomatic-carotid-stenosis>

U.S. Preventive Services Task Force. (2007). Screening for carotid artery stenosis: U.S. Preventive Services Task Force recommendation statement. *Annals of Internal Medicine*, 147(12), 854-859.

[Raman, G., Moorthy, D., Nadar, N., Dahabreh, I., O'Donnell, T., Thaler, D., et al. \(2013\). Management Strategies for Asymptomatic Carotid Stenosis. *Annals of Internal Medicine*, 158\(9\), 676-685.](#)

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

SUMMARY OF EVIDENCE

Clinical Background

Stroke is the third leading cause of death and probably the most important cause of long-term disability. The case fatality rate is between 15% and 35% with the first attack and rises to 65% for subsequent strokes. The majority of recurrences occur within one year and in the same anatomic region as the first stroke. Eighty-five percent of strokes are ischemic. Carotid endarterectomy was introduced in the 1950s and increasing numbers of patients have undergone this procedure over the last three decades.

There have been five randomized controlled trials of endarterectomy in patients with a recent symptomatic carotid stenosis. The first two studies were small, performed over 30 years ago, included a high proportion of patients with non-carotid symptoms and did not stratify results by severity of stenosis. In 1991, the Veterans Affairs trial (VACSP) reported a non-significant trend in favor of surgery but this trial was stopped early when the two largest trials, the European Carotid Surgery Trial (ECST) and the North American Symptomatic Carotid Endarterectomy Trial (NASCET) reported their initial results. The final reports for ECST and NASCET were published in 1998. The European Carotid Surgery Trial reported benefit from surgery only in patients with 80% to 99% stenosis, and further limited this to 90% to 99% stenosis in women. In contrast, NASCET reported significant benefit from surgery in patients with 50% to 99% stenosis. In the previous version of this review, an attempt was made to reconcile and pool these apparently conflicting results. However, the differences between the trial results were partly due to differences in the methods of measurement of the degree of carotid stenosis on the pre-randomization catheter angiograms; the method used in ECST producing higher values than the method used in the NASCET and VACSP trials. There were also other differences, such as in the definitions of outcome events. Only by detailed re-analysis of the individual patient data and reassessment of the original angiograms can the results be properly compared or combined. In this version of the review, we have also included a pooled analysis of individual patient data from the three largest trials, in which the original angiograms were reassessed and analyses done using the same method of measurement of stenosis and the same definitions of outcomes. Neither the ECST nor the NASCET were powered to determine the effect of surgery in subgroups. Subgroup analyses of pooled individual patient data from these two trials have greater power to determine subgroup-treatment interaction reliably and therefore several such clinically important analyses have been added in this review.

Evidence Review

The three trials noted above (NASCET, VACSP and ECST) were included in this review. As the trials differed in the methods of measurement of carotid stenosis and in

the definition of stroke, a pooled analysis of individual patient data on 6092 patients (35,000 patient years of follow-up) from all three trials was completed after reassessment of the carotid angiograms and redefinition of outcomes when needed.

Presently, up to 80% of all carotid endarterectomies are performed based on the findings of Doppler ultrasound (US). To assist with the translation of US findings to angiographically defined stenosis, a chart is included in Appendix D that correlates various characteristics of the US test to degree of stenosis.

Inclusion criteria were similar for all three trials, with minor differences. All patients were symptomatic (i.e., had recent (within the last four to six months) TIA or minor ischemic stroke in the territory of the artery that was stenotic). The control group was best medical therapy, which included aspirin (79-83%), lipid-lowering medications (8-16%), antihypertensives (60%) and other antithrombotics. The exact surgical intervention was left to the discretion of the surgeon, but all surgeries were classified as endarterectomy. There were no imbalances in baseline characteristics between surgical and medical groups in the original trials.

Crossovers (patients who were randomized to one group but elected the alternate therapy) were similar for patients randomized to surgical therapy who chose medical therapy instead (0 to 3.4%) but significantly different for medical to surgical crossovers, with 22.8% of patients in the NASCET crossing over to surgery, compared to 9.2% to 9.8% in the other two trials. However, the average time to cross over to the surgical treatment was over 500 days in the two largest trials.

On re-analysis, there were no statistically significant differences between the trials in the risks of any of the main outcomes (operative risk of stroke, stroke morbidity and death) in any of the stenosis groups for either treatment group. There were likewise no statistically significant differences between trials in the effects of surgery on the relative risks of the main outcomes at five year follow up. Therefore, further analyses were performed on pooled data.

For the purposes of analysis, patients were stratified based on the degree of carotid stenosis (< 30%, 30% to 49%, 50% to 69%, 70% to 99%, near occlusion). Sub-group analysis was undertaken based on gender, age (<65, 65-74, ≥ 75) and time from most recent event to randomization (<2 weeks, 2-4 weeks, 4 to 12 weeks or > 12 weeks), type of primary event (ocular, cerebral TIA, stroke), presence of diabetes, irregular or ulcerated carotid plaque and contralateral occlusion. All of these factors had a significant effect on the risk of ipsilateral stroke in the medical group with the exception of contralateral occlusion. Male gender, older age, decreased time from ischemic event, presence of diabetes or an ulcerated plaque and those presenting with cerebral (non ocular) events all had a higher risk.

Surgery increased the five-year risk of ipsilateral ischemic stroke in patients with less than 30% stenosis (N = 1746, absolute risk reduction (ARR) -2.2%, P = 0.05), had no significant effect in patients with 30% to 49% stenosis (N = 1429, ARR 3.2%, P = 0.6), was of marginal benefit in patients with 50% to 69% stenosis (N = 1549, ARR 4.6%, P = 0.04), and was highly beneficial in patients with 70% to 99% stenosis without near-occlusion (N = 1095, ARR 16.0%, P < 0.001). However, there was no evidence of benefit (N = 262, ARR -1.7%, P = 0.9) in patients with near-occlusions (defined as > 95% stenosis). The authors note that it is possible that intention to treat analysis may have underestimated the benefit of surgery in this group because of the relatively high rate of endarterectomy in follow up in the medical treatment group. However, the rate of endarterectomy was similarly high in the 70% to 99% stenosis group, and significant benefit with surgery was seen, making this explanation less likely.

Three of the prespecified subgroup analyses showed statistically significant differences. Benefit from surgery was greatest in men (no statistically significant benefit in women) and patients aged 75 years or over, although all age categories showed some benefit from surgery. Patients who were randomized within two weeks after their last ischemic event showed the greatest benefit from surgery, and there was decreasing benefit with increasing delay, with no benefit evident if the last ischemic event was more than 12 weeks previous. Overall, there was a 7% operative risk of death or any stroke within 30 days.

[\[Evidence Source\]](#)

Asymptomatic Patients – Surgery

A Cochrane review last updated in 2008 evaluated carotid endarterectomy in asymptomatic patients. Three trials with a total of 5223 patients were included. In these trials, the overall net excess of operation-related perioperative stroke or death was 2.9%. For the primary outcome of perioperative stroke or death or any subsequent stroke, patients undergoing CEA fared better than those treated medically (relative risk (RR) = 0.69, 95% confidence interval (CI) 0.57 – 0.83). Similarly, for the outcome of perioperative stroke or death or subsequent ipsilateral stroke, there was benefit for the surgical group (RR = 0.71, 95% CI 0.55 – 0.90). For the outcome of any stroke or death, there was a non-significant trend towards fewer events in the surgical group (RR = 0.92, 95% CI 0.83 – 1.02). Subgroup analyses were performed for the outcome of perioperative stroke or death or subsequent carotid stroke. CEA appeared more beneficial in men than in women and more beneficial in younger patients than in older patients although the data for age effect were inconclusive. There was no statistically significant difference between the treatment effect estimates in patients with different

grades of stenosis but the data were insufficient. Patients were randomized to surgery only if they had stenosis of 60% to 99% in two trials, or 50% to 99% in the other trial.

A technology assessment commissioned by the Agency for Healthcare Research and Quality addressed management strategies for asymptomatic carotid stenosis and was completed in 2013 (Raman 2013). This review included the same three RCTs comparing CEA to medical management as were included in the Cochrane review discussed above, as well as eight additional non-randomized studies. In addition, 26 cohort studies were included that evaluated the efficacy of medical therapy alone for asymptomatic carotid stenosis. Authors note that all patients in the RCTs were recruited before 2000 and did not receive what is currently considered best available medical therapy (primarily, statins). Meta-analysis of the three RCTs for the outcome of ipsilateral stroke found a lower risk in the CEA group (RR = 0.72 (95% CI 0.58, 0.90)¹ in long-term follow up (range of 2.7 to 10 years), although the periprocedural risk of any stroke was increased in the CEA group [RR = 5.94 (95% CI 2.06, 17.12)], as was death [RR 3.68 (95% CI 0.77, 17.72)]. There was no significant difference in the risk of any stroke or death, or death, between groups in long-term follow up.

Meta-analysis of the 26 cohort studies found an ipsilateral stroke incidence rate of 1.68% per year of follow up, and meta-regression showed that incidence was significantly lower in studies that completed recruitment between 2000 and 2010 than in those who completed recruiting prior to 2000 (1.13% vs. 2.38% per year, respectively). The authors conclude that “evidence from comparisons of CEA plus medical therapy versus medical therapy alone showed a reduction in the risk for ipsilateral stroke or any stroke with the combined approach. However, RCTs comparing CEA plus medical therapy with medical therapy alone recruited participants from the 1990s through early 2000. Medical therapy was suboptimal in these older RCTs by current standards, and findings of the RCTs may not be applicable to contemporary clinical practice.”

Asymptomatic Patients - Screening

The US Preventive Services Task Force issued recommendations pertaining to screening asymptomatic patients for carotid artery stenosis (CAS) in 2007. They concluded the following: The USPSTF recommends against screening for asymptomatic CAS in the general adult population. This is a grade D recommendation².

Benefits of Detection and Early Intervention

¹ While not presented in the publication, absolute risk reduction could be calculated, and was 1.92%, with a number needed to treat of 52.

² A description of the USPSTF grades can be found in Appendix C.

Good evidence indicates that in selected, high-risk trial participants with asymptomatic severe CAS, carotid endarterectomy by selected surgeons reduces the 5-year absolute incidence of all strokes or perioperative death by approximately 5%. These benefits would be less among asymptomatic people in the general population. For the general primary care population, the benefits are judged to be no greater than small.

The task force reached their conclusions regarding the benefits of early detection based on two of the three trials included in the reviews discussed above. They note important limitations in this evidence, including that the medical treatment group was poorly defined and did not include treatments now considered to be optimal medical management.

Harms of Detection and Early Intervention

Good evidence indicates that both the testing strategy and the treatment with carotid endarterectomy can cause harms. A testing strategy that includes angiography will itself cause some strokes. A testing strategy that does not include angiography will cause some strokes by leading to carotid endarterectomy in people who do not have severe CAS. In excellent centers, carotid endarterectomy is associated with a 30-day stroke or mortality rate of about 3%; some areas have higher rates. These harms are judged to be no less than small.

USPSTF Assessment

The USPSTF concludes that, for individuals with asymptomatic CAS, there is moderate certainty that the benefits of screening do not outweigh the harms.

[\[Evidence Source\]](#)

Evidence Summary

Endarterectomy is of some benefit for 50% to 69% symptomatic stenosis and highly beneficial for 70% to 99% stenosis without near occlusion. Benefit in patients with carotid near-occlusion is uncertain. These results are generalizable only to surgically-fit patients operated on by surgeons with low complication rates (less than 7% risk of stroke and death). Benefit from endarterectomy depends not only on the degree of carotid stenosis, but also on several other factors, including the delay to surgery after the presenting event. The benefit in asymptomatic patients is cannot be determined since trials were conducted before current best medical therapy was available. small.

The benefits of screening asymptomatic individuals do not outweigh the harms.

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
Carotid endarterectomy in symptomatic patients	<p>Harms exceed benefits in stenosis < 30%, ⊕</p> <p>No benefit in stenosis ≥ 30% but < 50%, ⊖</p> <p>Small benefit exceeds harms in stenosis ≥ 50% but < 70%, and</p> <p>⊖Substantial benefit in stenosis ≥ 70%</p>	High	Less costly when benefit exceeds harm, more costly when harm exceeds benefit	<p>Limited variability; most patients would opt for surgery when benefits exceed harms</p> <p>Moderate variability when stenosis ≥ 50% but < 70%</p>	<p>Carotid endarterectomy is recommended for coverage in patients with 70-99% carotid stenosis without near-occlusion <i>Strong Recommendation</i></p> <p>For patients with 50 – 69% carotid stenosis who are symptomatic (recent transient ischemic attack or ischemic stroke), carotid endarterectomy is recommended for coverage only for those who have failed optimal medical management <i>Weak Recommendation</i></p> <p>Carotid endarterectomy is not recommended for coverage for patients with less than 50% carotid stenosis</p>

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Values and preferences	Coverage Recommendation
Carotid endarterectomy in asymptomatic patients	<p>Unclear whether B benefit exceeds harms for stenosis > 60% when <u>compared to current best medical therapy performed in centers with complication rate of 3% or less</u></p> <p>Subgroup analysis based on degree of stenosis found no difference between groups, but because of the small number of events, was underpowered to detect such differences</p>	<p>High for benefit overall, low for differential effect based on degree of stenosis <u>Moderate compared to prior medical therapy, insufficient compared to current best medical therapy</u></p>	Less costly when benefit exceeds harm, more costly when harm exceeds benefit	<p>Limited <u>Moderate</u> variability, <u>given lack of clear evidence of benefit</u>; most patients would opt for surgery when <u>benefits exceed harms</u></p>	<p>Because the evidence had insufficient power to detect differences in effect based on degree of stenosis, and because it clinically seems unlikely that asymptomatic patients would derive greater benefit from surgery than symptomatic patients, coverage recommendations are similar to the symptomatic group</p> <p>Carotid endarterectomy is recommended for coverage in patients with 70-99% carotid stenosis without near-occlusion <i>Strong Recommendation</i></p> <p><u>Carotid endarterectomy is recommended for coverage for patients with asymptomatic carotid stenosis only for those who do not tolerate (or have contraindications to) best current medical therapy</u> <i>Weak Recommendation.</i></p> <p>Carotid endarterectomy is not recommended for coverage for patients with less than 50% carotid stenosis <i>Strong Recommendation</i></p>
Population	Benefits do not exceed harms	Moderate	Moderate	Moderate	Screening for asymptomatic carotid

Indication	Balance between desirable and undesirable effects	Quality of evidence*	Resource allocation	Values and preferences	Coverage Recommendation
screening for carotid stenosis			costs	variability; some patients would prefer screening, others would not	artery stenosis in the general primary care population is not recommended for coverage <i>Strong Recommendation</i>

Note: GRADE framework elements are described in Appendix A

DRAFT

POLICY LANDSCAPE

Four quality measures were identified when searching the [National Quality Measures Clearinghouse](#). Two are measures developed by the Agency for Healthcare Research and Quality (AHRQ), one is developed by the National Committee on Quality Assurance (NCQA) and one is from an Australian entity. None are National Quality Forum endorsed. The first three are listed below:

- AHRQ: Carotid endarterectomy volume: number of carotid endarterectomy discharges per hospital
- AHRQ: Carotid endarterectomy mortality rate: number of deaths per total number of carotid endarterectomy discharges
- NCQA: Frequency of selected procedures - carotid endarterectomy: number of carotid endarterectomy procedures per member month, per measurement year

COMMITTEE DELIBERATIONS – HTAS

HTAS confirmed a "weak recommendation" for patients with 50-69% stenosis based on the evidence and expert opinion, consistent with the following GRADE definition: the subcommittee concludes that the desirable effects probably outweigh the undesirable effects, but is not confident.

Based on expert input, the subcommittee also elected to add Appendix D, which includes a guide for converting Doppler Ultrasound readings to various levels of stenosis, since Doppler ultrasound is the preferred diagnostic tool in current practice.

The subcommittee elected not to define indications for screening for carotid artery stenosis, as there was no trusted evidence source which adequately defined populations for whom the screening would be appropriate.

After discussion, the subcommittee elected not to define coverage criteria for asymptomatic patients with 50-69% stenosis.

COMMITTEE DELIBERATIONS – VBBS

VbBS discussed the role of screening versus diagnostic examinations. It was clarified that the USPSTF recommendation against screening in the general population applied to "adults without neurological symptoms and without a history of transient ischemic attacks (TIA) or stroke." Given this, it was felt to be appropriate to include a screening guideline. VbBS proposed two guideline notes for the Prioritized List based on the HTAS recommendations.

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.

DRAFT

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	
433.1	Occlusion and stenosis of precerebral arteries; carotid
ICD-9 Volume 3 (Procedure Codes)	
38.02	Incision of vessel (embolectomy/ thrombectomy); other vessels of head and neck
38.12	Endarterectomy; other vessels of head and neck
CPT Codes	
35301	Thromboendarterectomy; carotid, vertebral, subclavian, by neck incision
93880	Duplex scan of extracranial arteries; complete bilateral study
HCPCS Level II Codes	
None	

Note: Inclusion on this list does not guarantee coverage

Appendix C. What the U.S. Preventive Services Task Force Grades Mean and Suggestions for Practice

Grade	Definition	Suggestions for Practice
A	The USPSTF recommends the service. There is high certainty that the net benefit is substantial.	Offer/provide this service.
B	The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial.	Offer/provide this service.
C	C The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is moderate or high certainty that the net benefit is small.	Offer/provide this service only if other considerations support offering or providing the service in an individual patient.
D	The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits.	Discourage the use of this service.
I	The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.	Read the clinical considerations section of USPSTF Recommendation Statement. If the service is offered, patients should understand the uncertainty about the balance of benefits and harms.

Appendix D. Supplemental Information for Quantification of Stenosis Based on Doppler Ultrasound

Consensus Panel Gray-Scale and Doppler US Criteria for Diagnosis of ICA Stenosis

Degree of Stenosis (%)	Primary Parameters		Additional Parameters	
	ICA PSV (cm/sec)	Plaque Estimate (%)*	ICA/CCA PSV Ratio	ICA EDV (cm/sec)
Normal	<125	None	<2.0	<40
<50	<125	<50	<2.0	<40
50-69	125-230	≥50	2.0-4.0	40-100
≥70 but less than near occlusion	>230	≥50	>4.0	>100
Near occlusion	High, low or undetectable	Visible	Variable	Variable
Total occlusion	Undetectable	Visible, no detectable lumen	Not applicable	Not applicable

*Plaque estimate (diameter reduction) using gray-scale and color Doppler US; ICA=internal carotid artery; CCA=common carotid artery; PSV=peak systolic velocity; EDV=end diastolic velocity

Extracted from Grant, E.G., Benson, C.B., Moneta, G.L., Alexandrov, A.V., Baker, J.D., Bluth, E.I., et al. (2003). Carotid artery stenosis: Gray-scale and Doppler US diagnosis – Society of Radiologists in Ultrasound Consensus Conference. *Radiology*, 229(2), 340-346.

Appendix E. HERC Guidance Development Framework – Carotid Endarterectomy Indications

Carotid Endarterectomy – Stenosis ≥ 70%, Carotid Endarterectomy – 50-69% Stenosis, Symptomatic



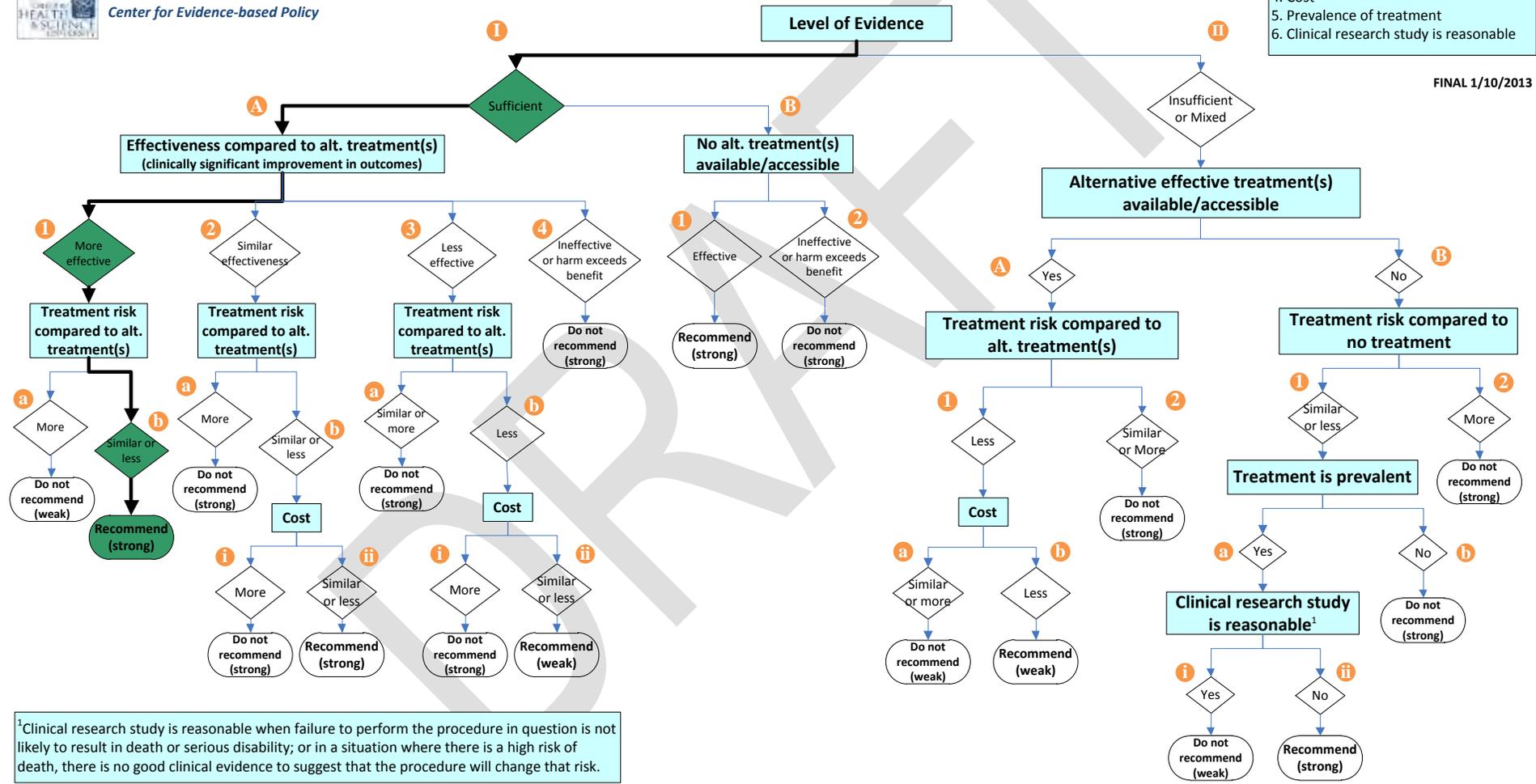
Center for Evidence-based Policy

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



¹Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Asymptomatic Carotid Stenosis

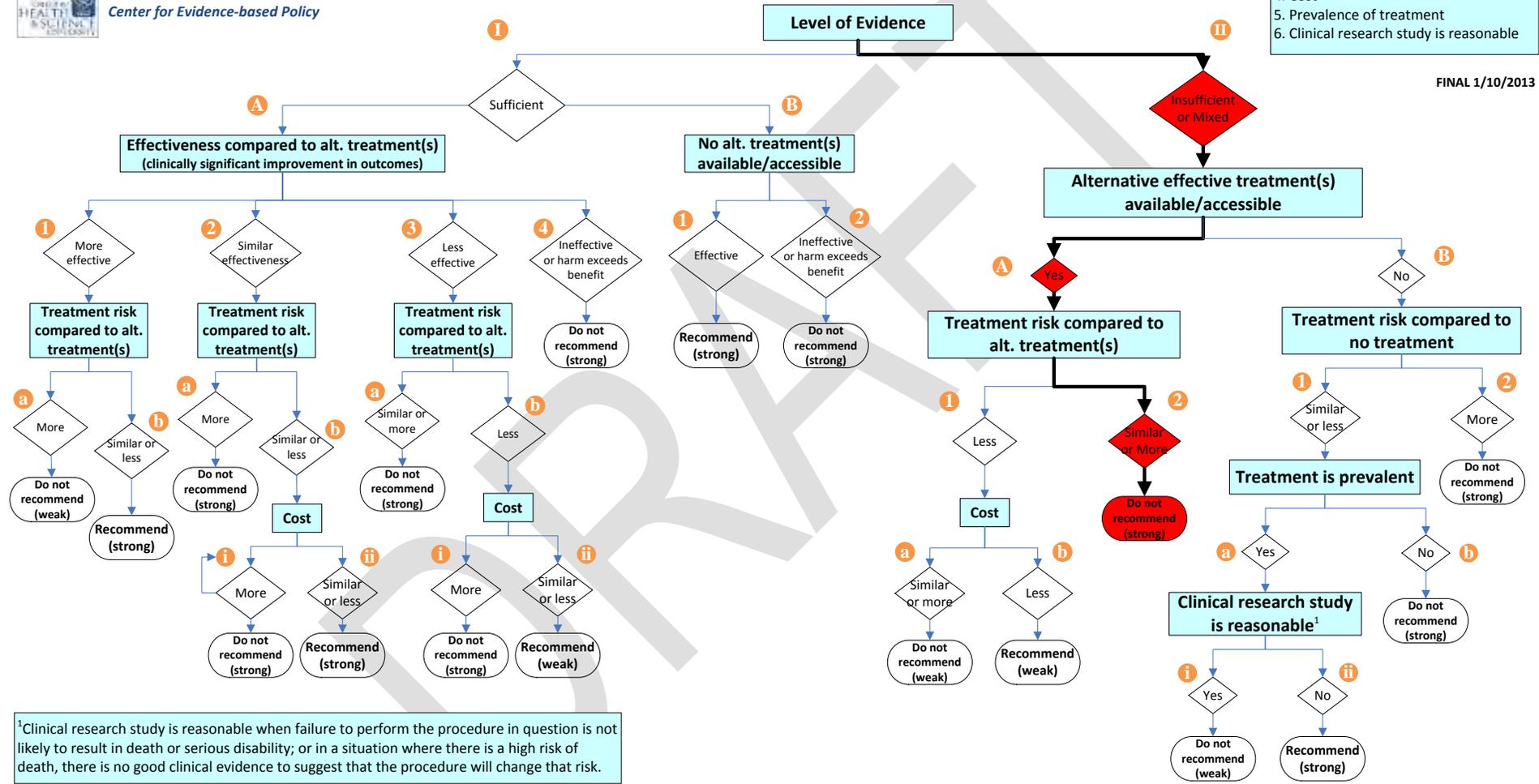


HERC Guidance Development Framework

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



¹Clinical research study is reasonable when failure to perform the procedure in question is not likely to result in death or serious disability; or in a situation where there is a high risk of death, there is no good clinical evidence to suggest that the procedure will change that risk.

Carotid Endarterectomy CG Application to Prioritized List

Question: How should the Coverage Guidance: CAROTID ENDARTERECTOMY VS. MEDICAL MANAGEMENT AND SCREENING FOR CAROTID ARTERY STENOSIS be applied to the Prioritized List?

Question Source: HTAS

Current Prioritized List status:

Line: 440
Condition: TRANSIENT CEREBRAL ISCHEMIA; OCCLUSION/STENOSIS OF PRECEREBRAL ARTERIES WITHOUT OCCLUSION (See Guideline Notes 64,65,76)
Treatment: MEDICAL THERAPY; THROMBOENDARTERECTOMY
ICD-9: 362.34,388.02,433.00,433.10,433.20,433.30,433.80,433.90,435.0-435.9,V12.54
CPT: 34001,35301,35390,37202,37215,37216,98966-98969,99051,99060,99070,99078,99201-99239,99281-99360,99366,99374,99375,99379-99412,99429-99444,99468-99480,99487-99496,99605-99607
HCPCS: G0396,G0397,G0406-G0408,G0425-G0427,S0270-S0274

Code	Code Description	Current Placement
93880	Duplex scan of extracranial arteries; complete bilateral study	DMAP Diagnostic Procedure File

Coverage Guidance:

Carotid endarterectomy is recommended for coverage for patients who are symptomatic (recent transient ischemic attack or ischemic stroke) and who have 70-99% carotid stenosis without near-occlusion (*strong recommendation*).

For patients with 50 – 69% carotid stenosis who are symptomatic despite optimal medical management, carotid endarterectomy is recommended for coverage (*weak recommendation*).

Carotid endarterectomy is not recommended for coverage for symptomatic patients with less than 50% carotid stenosis (*strong recommendation*).

Carotid endarterectomy is recommended for coverage for patients with asymptomatic carotid stenosis of at least 60 percent only for those who do not tolerate (or have contraindications to) best current medical therapy (weak recommendation).

Screening for asymptomatic carotid artery stenosis in the general primary care population is not recommended (*strong recommendation*).

HERC Staff Recommendations:

1) **Adopt a new diagnostic guideline:**

DIAGNOSTIC GUIDELINE XX SCREENING FOR CAROTID ARTERY STENOSIS

Screening for carotid artery stenosis (CPT 93880) in the general primary care population is not a covered service.

2) Adopt a new guideline note:

GUIDELINE NOTE XXX CAROTID ENDARTERECTOMY

Line 440

Carotid endarterectomy is included on line 440 for patients in the following groups:

- Symptomatic^[1] with 70-99% carotid artery stenosis but without near occlusion.
- Symptomatic with 50 – 69% stenosis despite optimal medical management
- Asymptomatic with at least 60% stenosis only for those who do not tolerate (or have contraindications to) best current medical therapy

Carotid endarterectomy is not included on line 440 for patients in the following groups:

- Patients with near occlusion
- Symptomatic patients with less than 50% carotid stenosis

^[1] Symptomatic patients are those who have had a recent transient ischemic attack or ischemic stroke

HERC Coverage Guidance – Carotid Endarterectomy vs. Medical Management and Screening for Carotid Artery Stenosis Disposition of Public Comments

Stakeholder	#	Comment	Disposition
	1	No public comments were received for this topic.	

Section 4.0

Coverage Guidances-EbGS

EbGS Coverage Guidance Summaries

Oregon Health Evidence Review Commission

December 5, 2013



Center for Evidence-based Policy

Coverage Guidance

For HERC review and approval:

- Treatment of Attention Deficit Hyperactivity Disorder in Children

Treatment of ADHD in Children

Draft HERC Coverage Guidance (Part 1)

Children under Age 6

- For children under 6 diagnosed with disruptive behavior disorders¹, including those at risk for ADHD, specific parent behavior training² is recommended for coverage as first-line therapy (*strong recommendation*).
- Pharmacotherapy³ is recommended for coverage as a second line therapy (*weak recommendation*).
- Provider consultation with teachers is recommended for coverage (*weak recommendation*).

¹Children with comorbid mental health conditions may require additional or different treatments that are not addressed in this guidance.

²Effective studied types of parent behavior training include: Triple P (Positive Parenting of Preschoolers) Program, Incredible Years Parenting Program, Parent-Child Interaction Therapy and New Forest Parenting Program. The term “parent” refers to the child’s primary care givers, regardless of biologic or adoptive relationship.

³Limited to medications that are FDA-approved for the condition.

Treatment of ADHD in Children

Draft HERC Coverage Guidance (Part 2)

Children Age 6 and Over

- For children 6 and over who are diagnosed with ADHD¹, pharmacotherapy³ alone (*weak recommendation*) or pharmacotherapy³ with psychosocial/behavioral treatment (*strong recommendation*) are recommended for coverage.
- Provider consultation with teachers is recommended for coverage (*weak recommendation*).

¹Children with comorbid mental health conditions may require additional or different treatments that are not addressed in this guidance.

³Limited to medications that are FDA-approved for the condition.

Treatment of ADHD in Children

Evidence Summary

Children under age six

- Effective treatment for preschoolers with disruptive behavior disorders
 - Parent behavior training
 - Psychostimulant medication
 - Classroom teacher consultations + parent behavior training for children of lower socioeconomic status
- Adverse events
 - None reported for parent behavior training
 - Some adverse effects with methylphenidate

Treatment of ADHD in Children

Evidence Summary, cont.

Children age six and over

- Long term effectiveness
 - Methylphenidate
 - Atomoxetine
 - Methylphenidate combined with behavioral/psychosocial interventions
- Short-term effectiveness
 - Other FDA approved medications
 - Guanfacine (more frequent adverse events)

Treatment of ADHD in Children

EbGS Deliberations

- Discussion of availability for behavioral/psychological treatments, for children under 6, including an additional literature search. No support found for other therapies besides parent training.
- Chose to remain silent on behavior treatments alone for children 6 and over without medication. No evidence to support this but implementation of restrictions would be challenging.
- Evidence for school based therapies addressed by adding coverage for provider/teacher consultations.

Treatment of ADHD in Children

VbBS Deliberations

Adopted a guideline note based on the Coverage Guidance.

Treatment of ADHD in Children

Draft HERC Coverage Guidance (Part 1)

Children under Age 6

- For children under 6 diagnosed with disruptive behavior disorders¹, including those at risk for ADHD, specific parent behavior training² is recommended for coverage as first-line therapy (*strong recommendation*).
- Pharmacotherapy³ is recommended for coverage as a second line therapy (*weak recommendation*).
- Provider consultation with teachers is recommended for coverage (*weak recommendation*).

¹Children with comorbid mental health conditions may require additional or different treatments that are not addressed in this guidance.

²Effective studied types of parent behavior training include: Triple P (Positive Parenting of Preschoolers) Program, Incredible Years Parenting Program, Parent-Child Interaction Therapy and New Forest Parenting Program. The term “parent” refers to the child’s primary care givers, regardless of biologic or adoptive relationship.

³Limited to medications that are FDA-approved for the condition.

Treatment of ADHD in Children

Draft HERC Coverage Guidance (Part 2)

Children Age 6 and Over

- For children 6 and over who are diagnosed with ADHD¹, pharmacotherapy³ alone (*weak recommendation*) or pharmacotherapy³ with psychosocial/behavioral treatment (*strong recommendation*) are recommended for coverage.
- Provider consultation with teachers is recommended for coverage (*weak recommendation*).

¹Children with comorbid mental health conditions may require additional or different treatments that are not addressed in this guidance.

³Limited to medications that are FDA-approved for the condition.

HEALTH EVIDENCE REVIEW COMMISSION (HERC)

COVERAGE GUIDANCE: TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER IN CHILDREN

DRAFT for HERC Meeting Materials 12/5/2013

HERC COVERAGE GUIDANCE

Children under Age 6

For children under 6 diagnosed with disruptive behavior disorders¹, including those at risk for ADHD, specific parent behavior training² is recommended for coverage as first-line therapy (*strong recommendation*).

Pharmacotherapy³ is recommended for coverage as a second line therapy (*weak recommendation*).

Provider consultation with teachers is recommended for coverage (*weak recommendation*).

Children Age 6 and Over

For children 6 and over who are diagnosed with ADHD¹, pharmacotherapy³ alone (*weak recommendation*) or pharmacotherapy³ with psychosocial/behavioral treatment (*strong recommendation*) are recommended for coverage.

Provider consultation with teachers is recommended for coverage (*weak recommendation*).

¹*Children with comorbid mental health conditions may require additional or different treatments that are not addressed in this guidance.*

²*Effective studied types of parent behavior training include: Triple P (Positive Parenting of Preschoolers) Program, Incredible Years Parenting Program, Parent-Child Interaction Therapy and New Forest Parenting Program. The term "parent" refers to the child's primary care givers, regardless of biologic or adoptive relationship.*

³*Limited to medications that are FDA-approved for the condition.*

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 SOURCE

American Academy of Pediatrics (AAP). (2011). Supplemental information. Implementing the key action statements: An algorithm and explanation for process of care for the evaluation, diagnosis, treatment, and monitoring of ADHD in children and adolescents. *Pediatrics*, S11-S121. Retrieved December 5, 2012, from <http://pediatrics.aappublications.org/content/128/5/1007/suppl/DC1>

Charach, A., Dashti, B., Carson, P., Booker, L., Lim, C.G., Lillie, E., et al. (2011). *Attention deficit hyperactivity disorder: Effectiveness of treatment in at-risk preschoolers; long-term effectiveness in all ages; and variability in prevalence, diagnosis, and treatment. Comparative effectiveness review no. 44.* (Prepared by the McMaster University Evidence-based Practice Center under Contract No. MME2202 290-02- 0020.) AHRQ Publication No. 12-EHC003-EF. Rockville, MD: Agency for Healthcare Research and Quality. Retrieved from www.effectivehealthcare.ahrq.gov/reports/final.cfm.

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

SUMMARY OF EVIDENCE

Clinical Background

Attention deficit hyperactivity disorder (ADHD) is a condition characterized by inattention, overactivity, and impulsivity. While ADHD can begin before children enter

school, it is most commonly identified and treated in primary school. Boys are classified with ADHD approximately twice as frequently as girls, and primary school–age children approximately twice as frequently as adolescents. ADHD symptoms exist on a continuum in the general population and are considered a “disorder” to a greater or lesser degree. Symptoms are clinically significant when they cause impaired functioning. The DSM-IV criteria include subtypes: (1) predominantly inattentive, (2) predominantly hyperactive-impulsive, and (3) combined inattentive and hyperactive.

Although the condition now classified as ADHD was first described clinically in 1902, few treatments were available until the 1950s, when methylphenidate (brand name, Ritalin) was developed to target the condition. The use of pharmacotherapy has increased through the years, along with refinements in understanding and recognition of the condition as a disorder. The diagnosis of ADHD and prescriptions for its treatment have grown exponentially, particularly in North America. By the end of the 1960s, approximately 150,000 to 200,000 children were treated with stimulants, which represented 0.002% of the U.S. child population at that time. In contrast, the U.S. National Survey of Child Health provides a 2003 estimate of 4.4 million children who were identified at some point as having ADHD, which represents 7.8% of that population, of which 2.5 million (56%) were receiving medication. Within the United States, the estimated prevalence of adult ADHD stands at 4.4%. Prescriptions for the treatment of ADHD have increased as well, with methylphenidate prescriptions increasing from 4 million to 11 million, and prescriptions for amphetamines increasing from 1.3 million to 6 million in an eight year period of time (1991-1999).

Drugs currently FDA approved for treatment of ADHD and their maximum recommended daily dosages are listed in Table 1. In addition, a variety of antidepressants are used off-label to treat this condition.

Table 1. FDA Approved Medications for the Treatment of ADHD

Drug Class/ Generic name	Brand names	FDA Approved max dose/day
<i>Amphetamine preparations</i>		
Mixed amphetamine salts	Adderall	40mg
	Adderall XR	30mg
Dextroamphetamine	Dexedrine, Dextrostat	40mg
	Dexedrine spanule	40 mg
Lisdexamfetamine	Vyvanse	70mg
<i>Methylphenidate preparations</i>		
Dexmethylphenidate	Focalin	20mg

Drug Class/ Generic name	Brand names	FDA Approved max dose/day
	Focalin XR	30mg
Methylphenidate HCL	Methylin, Ritalin, Ritalin LA, Ritalin SR, Metadate CD, Metadate ER	60mg
	Daytrana	30mg
	Concerta	54mg < 13 years/ 72mg ≥ 13 years ¹
SNRIs		
Atomoxetine	Strattera	1.4mg/kg or 100mg
Other		
Guanfacine extended release	Intuniv	4mg
Clonidine extended release	Kapvay	0.4mg/day

Evidence Review

The purpose of this review is to critically examine the effectiveness and adverse events of interventions in preschool children with clinically significant disruptive behavior and therefore at high risk for ADHD and to similarly examine the comparative long-term effectiveness and adverse events of interventions for ADHD.

Treatment of Preschoolers with Disruptive Behavior Disorders

For the management of preschoolers with disruptive behavior disorders, including children considered to be at risk for ADHD², evidence was grouped into two broad categories of treatment: behavioral interventions and psychostimulant medication. A total of 31 studies evaluated parent behavior training, which was primarily defined as one of four manualized programs³. Nearly all studies showed positive effects, and pooled results for eight good-quality studies also found a significant improvement in

¹ From AAP 2011 reference

² The ADHD diagnosis has not been widely applied in children under age 6 because of uncertainty regarding the reliability and validity of the diagnostic criteria in this age group. Because ADHD in this age group is commonly identified in the context of other disruptive behaviors, and in children with diagnoses of Disruptive Behavior Disorders including Oppositional Defiant Disorder and Conduct Disorder, the evidence review includes studies of children less than six with Disruptive Behavior Disorders.

³ Triple P (Positive Parenting of Preschoolers) Program, Incredible Years Parenting Program, Parent-Child Interaction Therapy and New Forest Parenting Program

child behavior with parent behavior training. In addition, the single good-quality study of methylphenidate finds that it appears to be effective. The strength of evidence for use of parent behavior training was judged high due to number of studies and consistency of results. The strength of evidence for methylphenidate was judged low because there is only one good-quality study.

Long-term extension (follow-up) studies for the RCTs of parent behavior training suggest that the benefits are maintained for several years, although no long-term study (lasting 12 months or more) of parent behavior training alone included untreated comparison groups, and attrition was high. A recent study examining parent behavior training with and without school-based teacher or child interventions included a no-treatment control. This study showed maintenance of benefits of parent behavior training at two years. Studies do not comment on adverse events related to parent behavior training.

Five studies examining combinations of parent behavior training and school or daycare interventions for preschool children at risk for disruptive behavior disorder and/or ADHD suggest that adding classroom teacher consultation may be important for children in low socioeconomic status (SES) communities, but not for families with educated parents who live in communities with resources, although direct comparisons of identical interventions offered to families of different SES have not yet been performed. All behavioral interventions showed benefits relative to no-treatment controls, and a dose response to the number of parent behavior training sessions attended by parents was also identified, enhancing the overall strength of evidence for effectiveness of parent behavior training.

Several small, short-term trials of psychostimulant medication use in preschoolers, primarily immediate release methylphenidate, suggest that it is efficacious and safe. In addition, the Preschool ADHD Treatment Study (PATs), a large, high quality trial funded by the National Institute of Mental Health also suggests that methylphenidate is effective for improving parent-rated child behavior in preschoolers. This multisite trial had multiple phases, beginning with 10 sessions of parent behavior training. The training was followed by an open label safety lead-in phase of a psychostimulant medication, then a titration phase, a cross-over phase and open-label maintenance phase that lasted 10 months. The PATs study offers information about both the potential benefits and limitations of stimulant medication use in very young children. Limitations include the following: preschool children experience more dose-related adverse events than older children, stimulants interfere with rates of growth, and the presence of three or more comorbid conditions and psychosocial adversity are associated with lessened effectiveness of psychostimulant medication. These findings are supported by two additional “fair” quality RCTs.

In conclusion, both parent behavior training and psychostimulant medication are effective treatment for preschoolers with disruptive behavior disorders. There are no adverse events reported for parent behavior training, while there are adverse effects with methylphenidate. This favors the use of parent behavior training for preschoolers at risk for ADHD due to disruptive behavior. A direct comparison has not yet been done.

Long-Term Effectiveness and Safety of Interventions in People Age 6 and Older

Pharmacologic Agents

The long-term effectiveness and safety (at least 12 months of treatment and/or follow up) of several psychostimulants (e.g., methylphenidate immediate release amphetamine, Osmotic-controlled Release Oral delivery System methylphenidate, dextroamphetamine, mixed amphetamine salts, atomoxetine, clonidine and guanfacine extended release) have all been examined prospectively in children and adolescents age 6 and over. The agents examined were all shown to be efficacious for control of inattention, overactivity, and impulsiveness for at least 12 months and up to three years, and few serious adverse events were noted, although guanfacine extended release appears to be less well tolerated than other agents examined. Global ratings of impairment also indicate continued benefit throughout the extension studies for patients still receiving medications. In general, those who remain on medication show continued benefit, and few adverse events are reported for them. With a majority of the studies funded by industry (12 of 21), there may be enhanced representations of effectiveness and safety. Psychostimulants continue to provide control of ADHD symptoms and are well tolerated for months to years at a time.

Fewer children experienced adverse events with methylphenidate than with dextroamphetamine. Concerns about adverse events led to discontinuation of medications for 15% to 20% of children age 6 and over using extended release mixed amphetamine salts. Concerns about exacerbation of tics with stimulants appear to be unfounded, although the sample size remains small. Use of psychostimulants slows the rate of growth, and increases blood pressure and heart rate to a small degree. At a group level, the mean changes are clinically insignificant, although on rare occasions individuals discontinue an agent because of changes in vital signs. There are many similarities between methylphenidate immediate release and other preparations of psychostimulants, both in terms of efficacy and in the side effect profile. Therefore, many researchers and clinicians assume all psychostimulants are effective and safe for extended periods of time. The documentation for this assertion is not yet robust.

Atomoxetine is both safe and effective for ADHD symptoms over 12 to 18 months among children and for up to three years in adults. Discontinuation in children and teens appears to be higher (26%) due to ineffectiveness and lower (3%) due to adverse events than with other agents, although these are not direct comparisons. As with

psychostimulants, the group means for blood pressure and heart rate show small but clinically insignificant increases. There is only one study of a pharmacologic intervention over an extended time period (three years) in adults with ADHD, and that study found symptom improvement was maintained for those on atomoxetine, and discontinuation due to adverse events was somewhat higher for adults (11%) than for children (3%).

An extension study of guanfacine suggests that this agent is also effective in controlling ADHD symptoms for up to two years; however, high rates (40% to 60%) of somnolence, headache, and fatigue occur when it is used as a monotherapy, especially in the initial six to eight months of treatment. A second study examined concurrent use of psychostimulants and noted improved tolerance to these adverse effects. Changes in vital signs occur, but no clear group trends are noted. Individuals may develop clinically significant hypotension and bradycardia. Serious adverse events include syncope and clinically significant changes on electrocardiogram.

Overall, pharmacologic agents used for controlling the symptoms of inattention, overactivity, and impulsivity of ADHD show maintenance of effectiveness and safety for 12 to 24 months. Following that, attrition from use interferes with the ability to draw conclusions. Along with decreased symptoms, overall functioning is improved.

Psychosocial and Behavioral Interventions, Alone and in Combination with Medication
Investigations comparing psychosocial/behavioral interventions, alone and in combination with psychostimulant medication management, showed that both medication and combined medication/behavioral treatment (including school-based interventions) are more effective in treating ADHD and oppositional defiant disorder symptoms than psychosocial or behavioral interventions alone. Psychosocial interventions in the four included trials included intensive behavioral treatment (parent behavior training, child-focused treatment and a school-based intervention), multimodal treatment (parent behavior training, behavior management training, family therapy and child social skills training), “behavior treatment” (undefined) and EEG biofeedback.

Longer Term Outcomes

Evaluation of long-term outcomes (five or more years follow up) following interventions for ADHD is complex due to multiple patterns of services used and very few studies available, with only two RCTs of well-characterized clinical samples, both of boys ages 7 to 9 years with DSM-IV ADHD, combined subtype. The best quality data come from the Multimodal Treatment of ADHD Study, which compared 14 months of management with immediate release methylphenidate to three other interventions: psychosocial and behavioral treatment; the combination of medication management and psychosocial and behavioral treatment; and standard community care. Three years after initiation, the four intervention groups showed comparable outcomes. No clear relationship was identified between duration of medication use and psychiatric or overall functional outcomes at

three years or beyond. In contrast, a few long-term cohort studies lasting five years or more suggest that increased duration of medication was associated with improved grade retention and academic achievement. No prospective studies have been designed to investigate the question of long-term functional outcomes directly. There appear to be long-term academic benefits with medication interventions in some domains.

In conclusion, the evidence for long-term effectiveness of pharmacologic agents for improving ADHD symptoms is based on a single good study for methylphenidate and a single good study for atomoxetine. These studies followed the children for 12 or 14 months and showed benefit with few adverse effects, thereby resulting in low strength of evidence for longer term effectiveness for each of these agents. Similarly, there is a single good study showing benefits for the combination of methylphenidate and psychosocial interventions. The evidence for other pharmaceutical agents is insufficient, as is the evidence pertaining to parent behavior training and academic interventions.

[\[Evidence Source\]](#)

Evidence Summary

For children under age six, both parent behavior training and psychostimulant medication are effective treatment for preschoolers with disruptive behavior disorders. Classroom teacher consultations in addition to parent behavior training are beneficial to children of lower socioeconomic status. There are no adverse events reported for parent behavior training, while there are adverse effects with methylphenidate.

In children age six and over, there is evidence to support the long-term effectiveness of both methylphenidate and atomoxetine for improving ADHD symptoms, as well as methylphenidate combined with behavioral/psychosocial interventions. There is evidence for only the short-term effectiveness for other FDA approved medications and guanfacine, the latter of which has more frequent adverse events.

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
Pharmacologic treatment age <6	net benefit, despite some harms	low	modest costs	likely moderate variability in parent preferences for treatment	Pharmacotherapy is recommended for coverage as a second line therapy <i>(weak recommendation)</i>
Parent Behavior Training (PBT) age <6	net benefit without apparent harms	high	modest costs	likely moderate variability in parent preferences for treatment	Specific parent behavior training is recommended for coverage as first-line therapy <i>(strong recommendation)</i>
Behavioral/ psychosocial treatment age <6 (excluding PBT)	no evidence	insufficient	modest costs	likely moderate variability in parent preferences for treatment	<i>No recommendation</i>
Pharmacologic treatment alone and combined with behavioral/ psychosocial interventions age ≥ 6	net benefit, despite some harms	low	modest costs	likely moderate variability in parent preferences for treatment	Pharmacotherapy alone (<i>weak recommendation</i>) or pharmacotherapy with psychosocial/ behavioral treatment (<i>strong recommendation</i>) are considered first-line therapy and are recommended for coverage

Indication	Balance between desirable and undesirable effects	Quality of evidence	Resource Allocation	Values and preferences	Coverage Recommendation
Behavioral/ psychosocial treatment alone, PBT, academic interventions age ≥ 6	unable to draw conclusions	insufficient	modest costs	likely moderate variability in parent preferences for treatment	Behavioral/ psychosocial treatment alone, PBT, academic interventions age ≥ 6 for primary ADHD are not recommended for coverage <i>(weak recommendation)</i>
School/ daycare based interventions	net benefit in those <6 of low SES, benefit in ≥ 6 as element of intensive behavioral treatment, no apparent harms	low	modest costs	likely minimal variability in parent preferences	School/daycare based interventions are outside the purview of this coverage guidance (<i>No recommendation</i>) Provider consultation with teachers is recommended for coverage (based on evidence of children <6 with low SES) <i>(weak recommendation)</i>

*The Quality of Evidence rating was assigned by the primary evidence source, not the HERC Subcommittee

Note: GRADE framework elements are described in Appendix A

POLICY LANDSCAPE

Five quality measures were identified when searching the [National Quality Measures Clearinghouse](#). The Institute for Clinical Systems Improvement developed three measures around diagnosis and management of attention deficit hyperactivity disorder (ADHD) in primary care for school age children and adolescents: 1) Percentage of patients diagnosed with ADHD whose medical record contains documentation that the clinician discussed the need for school-based supports and educational service options for children with ADHD; 2) Percentage of patients treated with psychostimulant medication for the diagnosis of ADHD whose medical record contains documentation of a follow-up visit at least twice a year; and 3) Percentage of patients newly diagnosed with ADHD whose medical record contains documentation of DSM-IV-TR or DSM-PC criteria. These three measures have not been endorsed by the National Quality Forum (NQF).

The National Committee for Quality Assurance developed two HEDIS measures, which are both endorsed by the NQF: 1) Follow-up care for children prescribed ADHD medication (initiation phase): percentage of members 6 to 12 years of age with an ambulatory prescription dispensed for ADHD medication, who had one follow-up visit with a practitioner with prescribing authority during the 30-day initiation phase; and 2) Follow-up care for children prescribed ADHD medication (continuation and maintenance [C&M] phase): percentage of members 6 to 12 years of age with an ambulatory prescription dispensed for ADHD medication, who remained on the medication for at least 210 days and who, in addition to the visit in the initiation phase, had at least two follow-up visits with a practitioner within 270 days (9 months) after the initiation phase ended.

Oregon's Coordinated Care Organizations' quality of care objectives include the following measure: Meet or exceed the 90th percentile national Medicaid benchmarks for follow up care for children on ADHD medication.

COMMITTEE DELIBERATIONS – EVIDENCE-BASED GUIDELINE SUBCOMMITTEE

The Evidence-based Guidelines Subcommittee had extensive deliberations on the types and availability of behavioral and psychology treatments available. An additional literature search was performed to determine if additional types of interventions had evidence to support beyond the parent behavioral training, and none were found. The decision was also made to remain silent on the treatment of children over 6 with behavioral treatments alone, due to implementation considerations. Subcommittee members determined the best way to address the coordination with teachers for school-based interventions was through communication/coordination between the provider and teacher being recommended as a covered service.

COMMITTEE DELIBERATIONS – VALUE-BASED BENEFITS SUBCOMMITTEE

The VbBS approved the draft coverage guidance and updated its guideline note on ADHD at its meeting 8/8/2013.

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 Framework Description

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
Costs (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	
312.9	Unspecified disturbance of conduct
314	Hyperkinetic syndrome of childhood
314.0	Attention deficit disorder of childhood
314.00	Attention deficit disorder without mention of hyperactivity
314.01	Attention deficit disorder with hyperactivity
314.1	Hyperkinesis with developmental delay
314.2	Hyperkinetic conduct disorder
314.8	Other specified manifestations of hyperkinetic syndrome
314.9	Unspecified hyperkinetic syndrome
ICD-9 Volume 3 (Procedure Codes)	
None	
CPT Codes	
90785	Interactive complexity, add-on code to be used in conjunction with codes for primary service
90791	Psychiatric diagnostic evaluation (no medical services)
90792	Psychiatric diagnostic evaluation (with medical services)
90832	Psychotherapy, 30 minutes with patient and/or family member
90834	Psychotherapy, 45 minutes with patient and/or family member
90837	Psychotherapy, 60 minutes with patient and/or family member
90839	Psychotherapy for crisis, first 60 minutes
90840	Add-on for each additional 30 minutes of psychotherapy for crisis, used in conjunction with code 90839
90845	Psychoanalysis
90846	Family psychotherapy without the patient present
90847	Family psychotherapy, conjoint psychotherapy with the patient present
90849	Multiple-family group psychotherapy
90853	Group psychotherapy (other than of a multiple-family group)
90863	Pharmacologic management, including prescription and review of medication, when performed with psychotherapy services; used only as add-on to primary psychotherapy code
98960	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; individual patient
98961	2-4 patients
98962	5-8 patients
HCPCS Codes	
H2027	Psychoeducational service, per 15 minutes
S9444	Parenting classes, non-physician provider, per session
S9482	Family stabilization services, per 15 minutes
T1027	Family training and counseling for child development, per 15 minutes

Note: Inclusion on this list does not guarantee coverage

Appendix C. HERC Guidance Development Framework – ADHD Indications

Pharmacologic Treatment age <6 as 1st Line Therapy

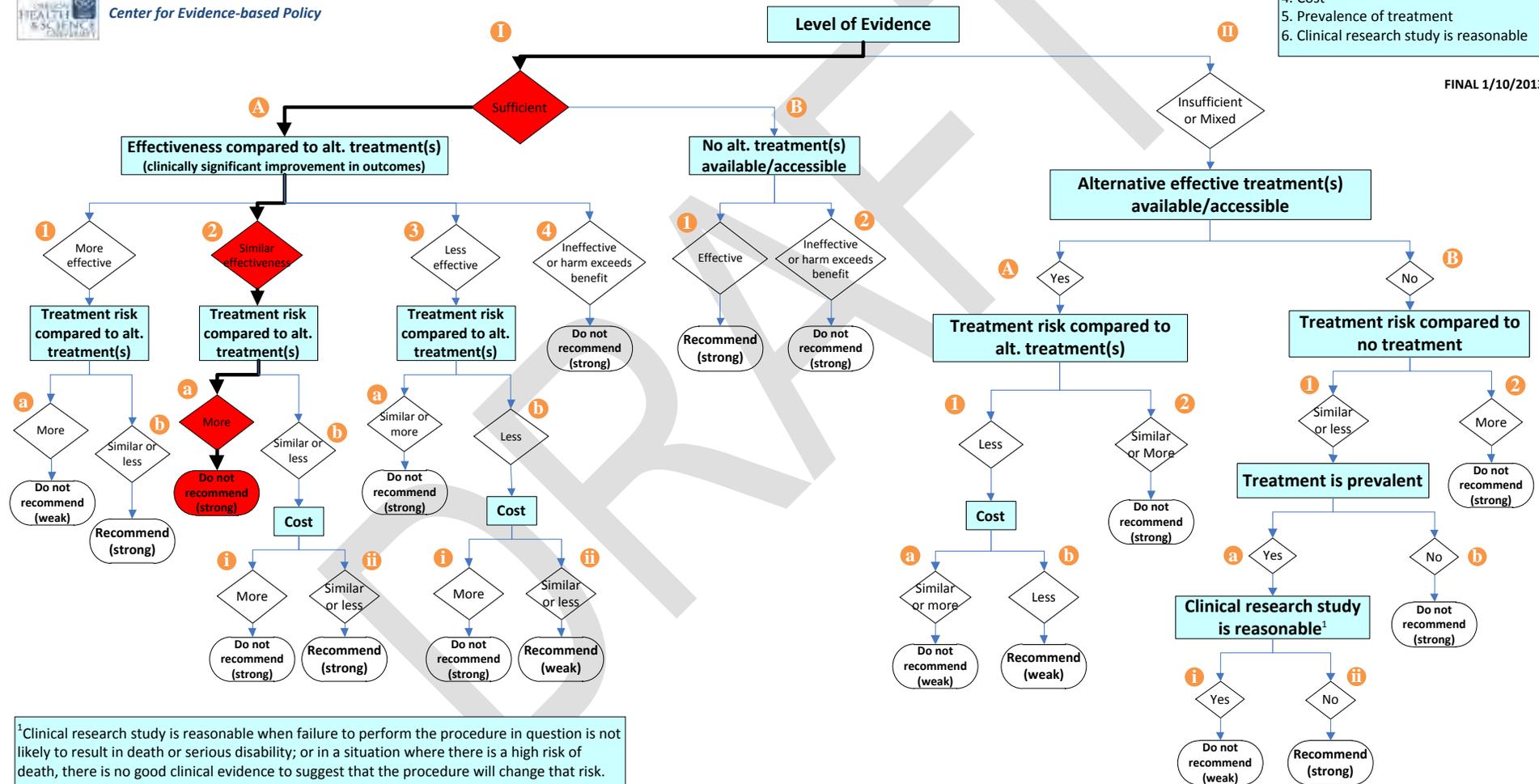


HERC Guidance Development Framework

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



Pharmacologic Treatment age <6 as 2nd Line Therapy

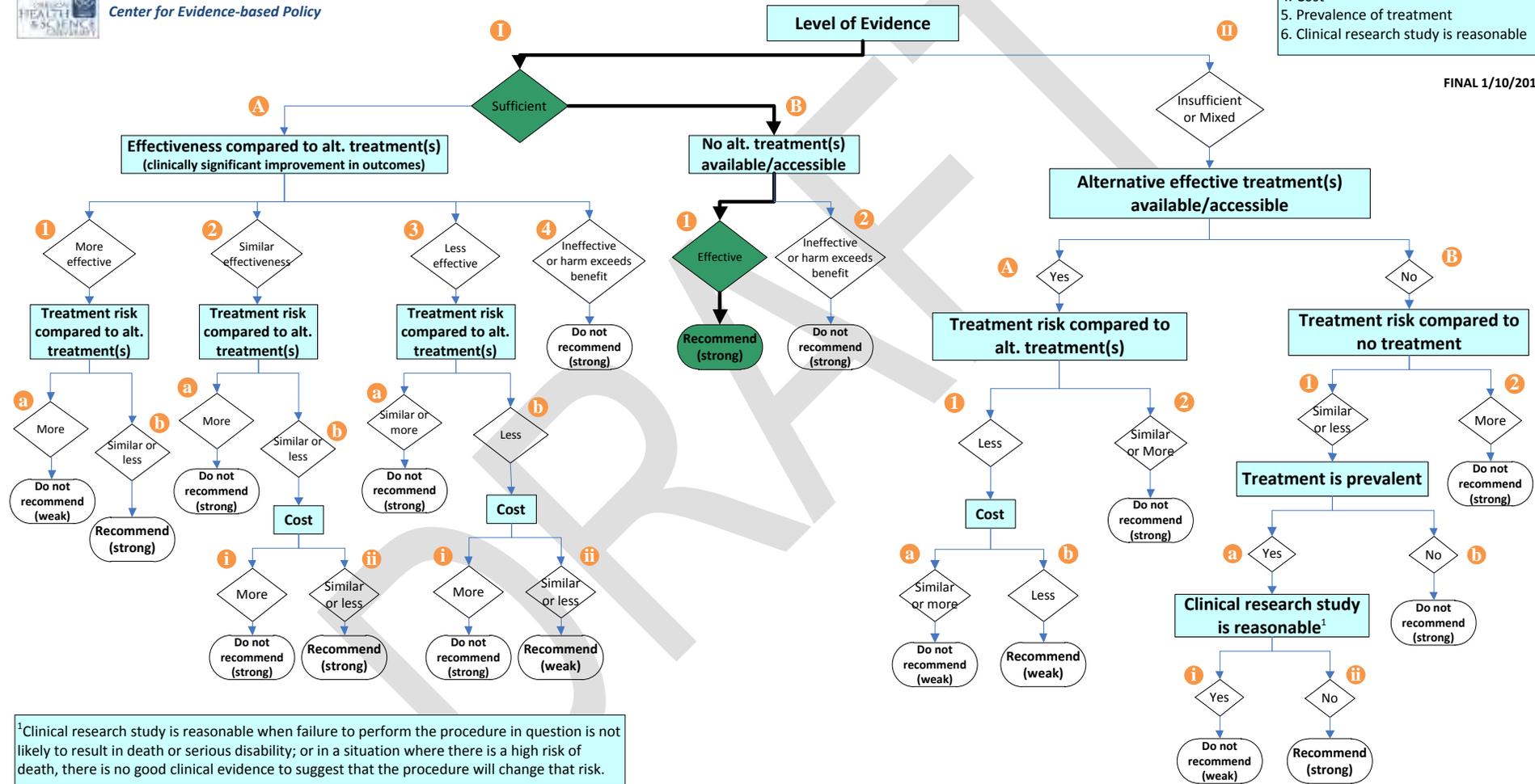


HERC Guidance Development Framework

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



Parent Behavior Training (PBT) or School/Daycare Interventions age <6 Compared to Pharmacologic Treatment

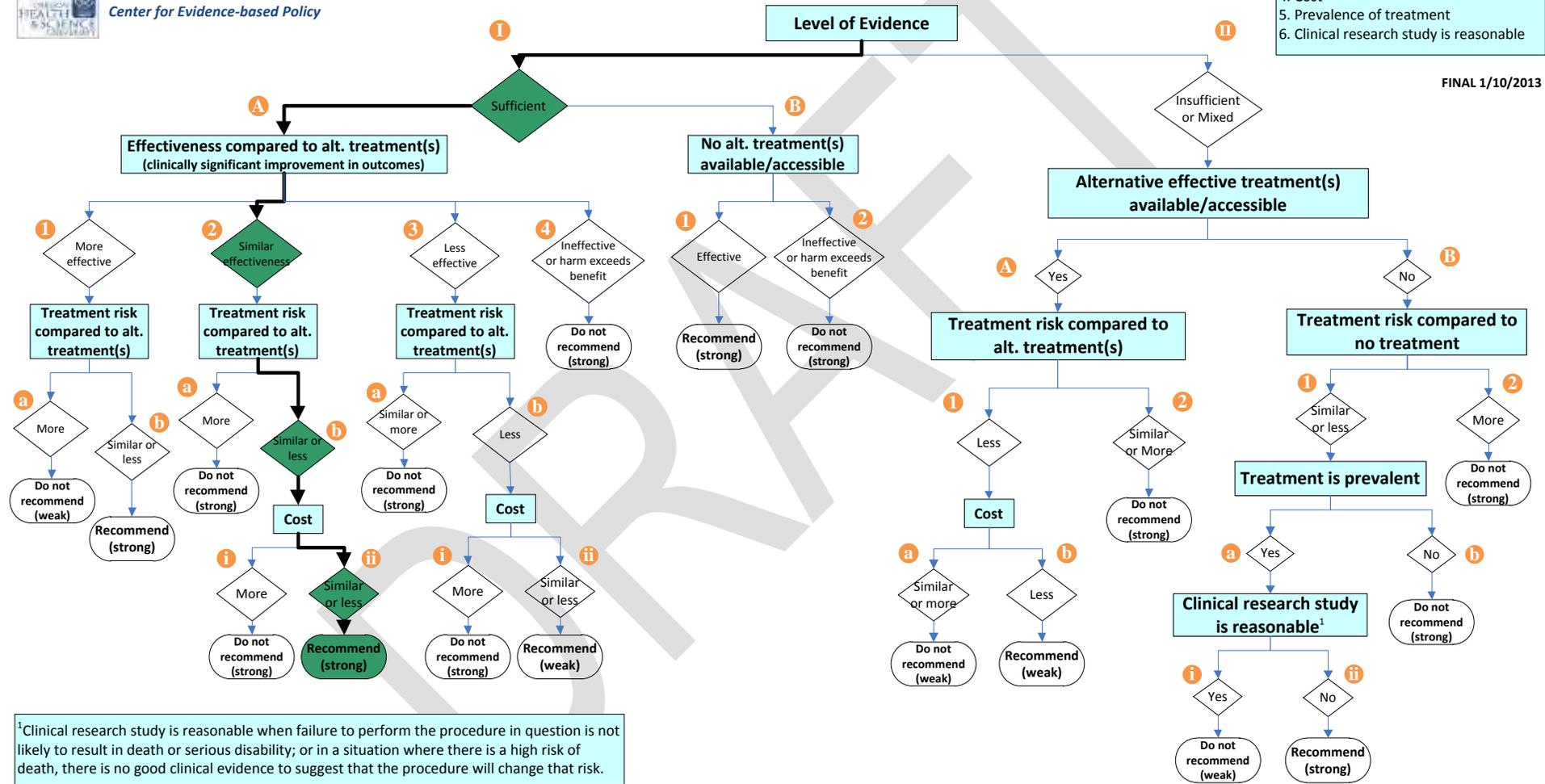


HERC Guidance Development Framework

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



Pharmacologic Treatment Alone and Combined with Behavioral/Psychosocial Interventions Age ≥ 6

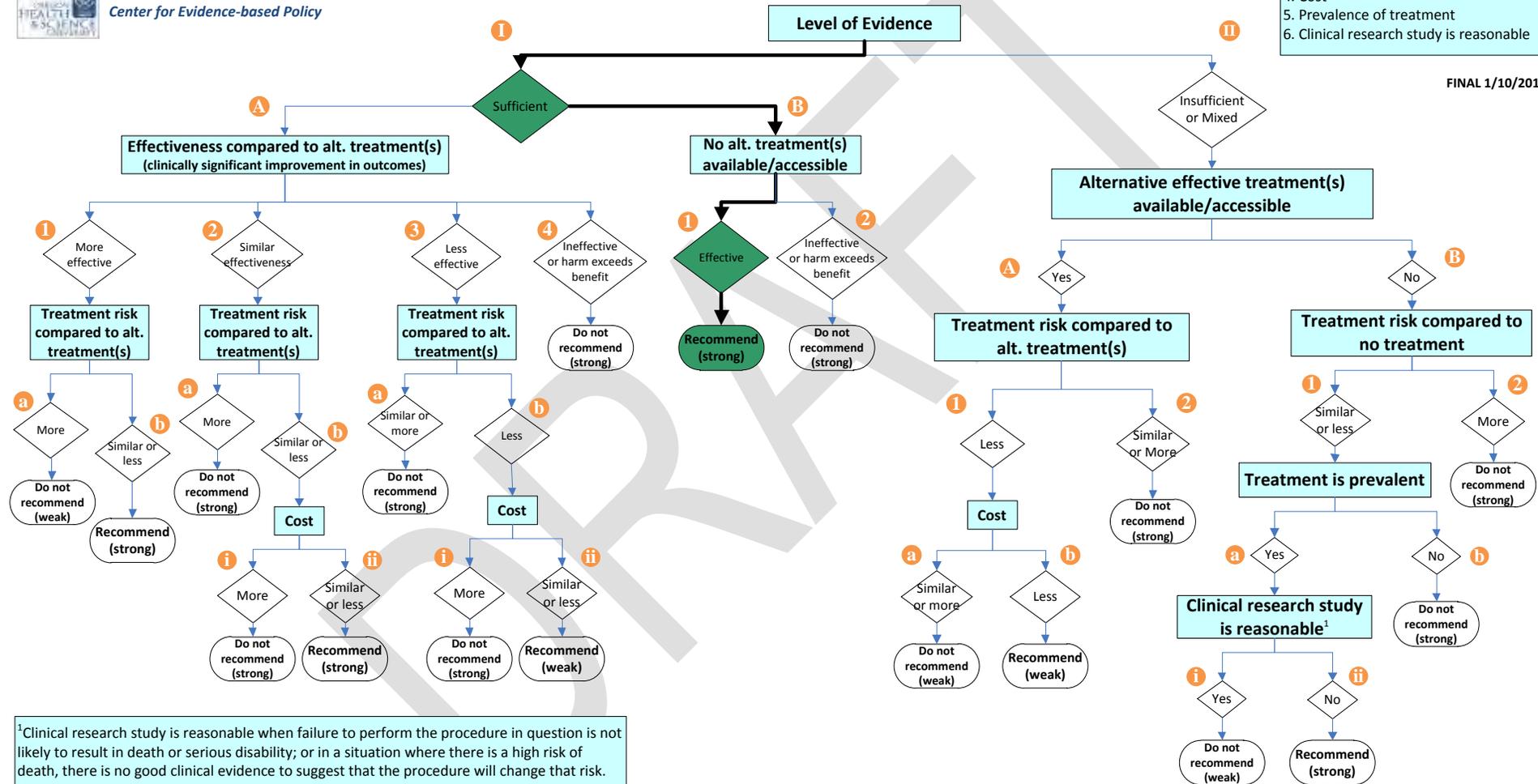


HERC Guidance Development Framework

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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Behavioral/Psychosocial Treatment Alone, PBT, Academic Interventions Age ≥ 6 Compared to Pharmacologic Treatment

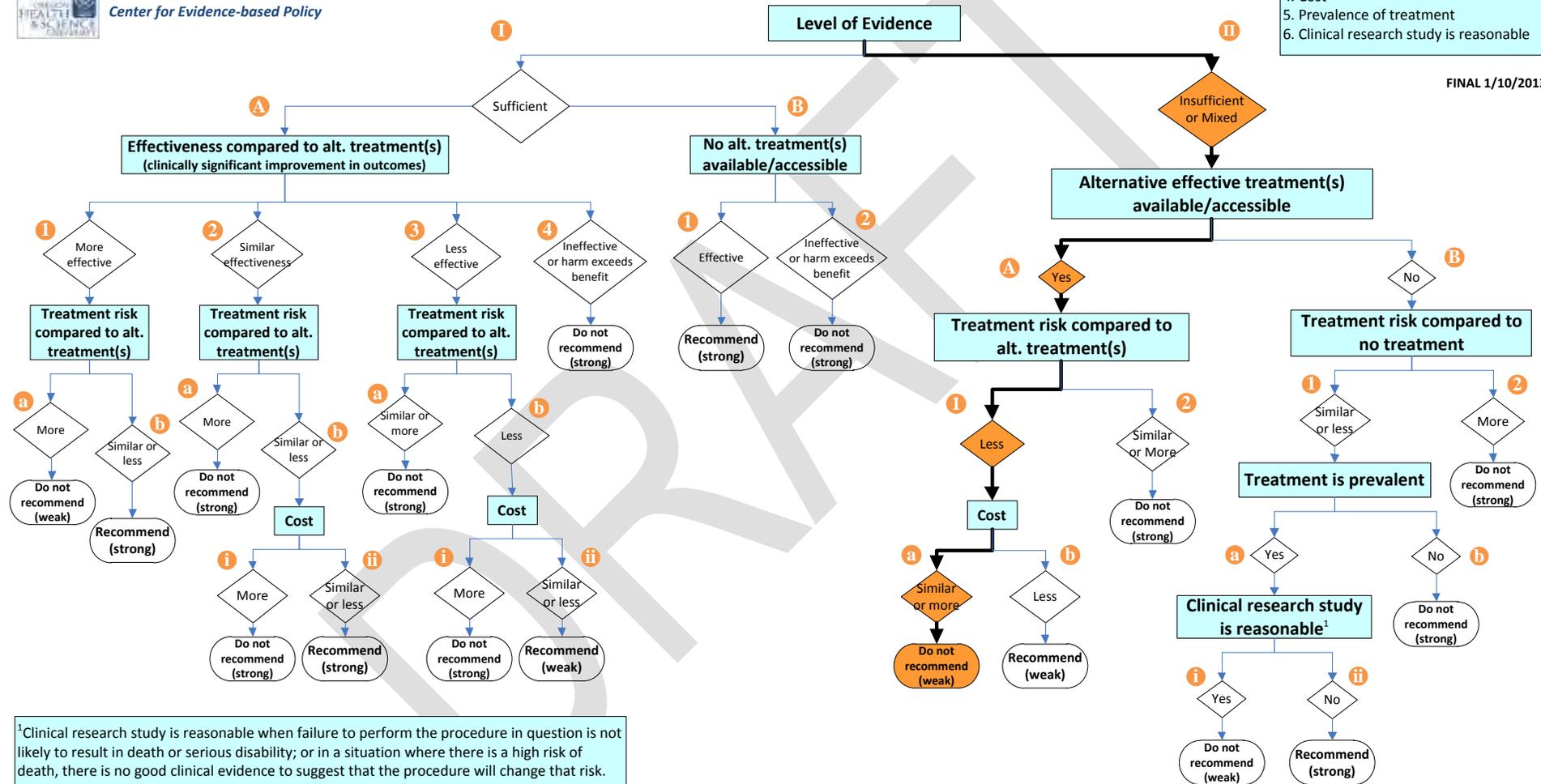


HERC Guidance Development Framework

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



GUIDELINE NOTE 20, ATTENTION DEFICIT AND HYPERACTIVITY DISORDERS IN CHILDREN AGE FIVE AND UNDER

Line 133

When using 314.9, Unspecified Hyperkinetic Syndrome, in children age 5 and under, it is appropriate only when the following apply:

- Child does not meet the full criteria for the full diagnosis because of their age.
- For children age 3 and under, when the child exhibits functional impairment due to hyperactivity that is clearly in excess of the normal activity range for age (confirmed by the evaluating clinician's observation, not only the parent/caregiver report), and when the child is very limited in his/her ability to have the sustained periods of calm, focused activity which would be expected for the child's age.

First line therapy is "parent-behavior training" (i.e. Triple P (Positive Parenting of Preschoolers) Program, Incredible Years Parenting Program, Parent-Child Interaction Therapy and New Forest Parenting Program). The term "parent" refers to the child's primary care givers, regardless of biologic or adoptive relationship.

Second line therapy is pharmacotherapy.

Use of 314.9 for children age five and younger is limited to pairings with the following procedure codes with first and second line therapy as denoted above:

- Assessment and Screening: 90791, 90792, H0002, H0031, H0032, T1023
- Family interventions and supports: 90832-90838, 90846, 90847, 90849, 90887, H0038, H0045, H2021, H2022, H2027, S5151, S9125, T1005
- Group therapy: 90785, 90832-90838, 90853, 99201-99215, H2032
- Medication management: 90832-90838, 99201-99215
- Case Management: 90882, T1016
- Provider/teacher care coordination: 99366, 99367, 99368
- Interpreter Service: T1013

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Expert Comments

Expert	#	Comment	Disposition
Ajit Jetmalani	1	Practice based evidence is as important as evidence based practice in the world of Medicaid insured individuals where there is a much higher incidence of psychosocial stress / trauma / comorbid psychiatric disorders and genetic risks and developmental challenges. As you know, these comorbid interactive conditions are rarely considered in the evidence base practice populations.	The EbGS agrees that the population considered in the evidence report is narrow and likely excludes most patients with comorbidities
	2	So, in fact, if a child with multiple comorbid conditions came in with ADHD / disruptive behavior disorder over age six, a competent clinician would indeed institute non pharmacologic therapy <i>first</i> . After making certain that the child is in a safe home, they might implement trauma CBT, Collaborative Problem Solving (an AMH approved practice) training for the parent / foster family and then rule out a learning issue before ever getting to medication as an option. To make the recommendations more effective, could add some language such as: "primary ADHD without comorbid diagnoses" ..or .."where ADHD symptoms occur in the context of trauma or complex clinical presentations, ADHD may be secondary and medical treatment should await diagnostic clarification and or non medical strategies".	The EbGS agrees that this guidance is limited to patients without comorbidity; clarification added to the box
	3	In the case of a child who is living in a home with an abusive parent (noted by the psychologist), obviously, safety and then trauma needs to be addressed if ADHD symptoms will every be correctly treated.	The EbS agrees, this would represent a comorbid condition which should be treated first.
Joel Nigg, Ph.D., Professor Director, Division of Psychology	4	For children under 6, parent training as first line, pharmacotherapy as second line, is correct. I would however allow a stronger support for teacher/day care consultation in cases where parents are ineffective regardless of SES	Thank you for your comment. Teacher/daycare consultation is beyond the scope of this guidance.
Department of Psychiatry	5	Recs for older children are also sensible but again, allow for school consultation as it is proven effective and I would not limit this based on SES, because there is so much variation in school and parent skill even within SES	See comment #4.
Oregon Health	6	Regarding the psychologists concern about exceptional cases where there is a lot of abuse, domestic violence, or PTSD in younger children, I think both sides have a valid point. It is true that the evidence base for effectiveness of individual therapy (CBT, or other)	See comment #2

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Expert Comments

Expert	#	Comment	Disposition
& Science University		with children with ADHD is negative, but for children with trauma the evidence is really sparse and one can find clinical experience that it provides meaningful support to ease suffering for children. It might make sense to allow this in some cases with adequate justification/documentation.	
	7	The 4.4% prevalence of ADHD in adults from Kessler et al NCS study has been challenged. Other studies (Simon et al) suggest more like 2.5%	Thank you for this information. As this was extracted directly from the AHRQ report and does not directly impact guidance rationale, the EbGS has elected not to change it.
	8	ADHD was first described by Benjamin Rush in 1812 in the USA; and was described by physicians in Europe in the 1800's. I would not cling to the 1902 citation for first description	See comment #7.
	9	What is the role of assessment? This is not clear in the guideline and perhaps is beyond their scope.	This document is not intended to serve as a practice guideline. Assessment is beyond the scope of the document.
	10	In the MTA study, the medication treatment group outperformed the community treatment group and had a higher success rate, by a lot, in the first year. This was attributed to the opportunity for 2 weeks dose and med titration. This would suggest that insurance should support dose titration and obtaining of blind ratings by teachers/parents and/or use of placebos during run-in, to ensure optimal dosage	See comment #9.
	11	Psychological and neuropsychological assessment can be a valuable guide to educational planning, e.g., when children have significant problems in executive functioning, memory, learning, or attention or have a non-verbal learning pattern that can be used by special education staff. Should insurance allow for targeted neuropsychological evaluation in cases of ADHD that are marked by significant learning failure despite treatment?	See comment #9.

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Public Comments

General Comments

Stakeholder	#	Comment	Disposition
<i>Pediatrician</i> Salem, OR	1	This on the whole appears to be well thought out incorporation of the latest information on ADHD treatment for children. Three areas of clarification I would request: 1. Clarity around the age. Guideline is written to say older than 6. I interpret this as 7 years or older. The latest ADHD guideline separates recommendations prior to 6th birthday or after 6th birthday. Simple clarification could be "6 years and older" when age is referenced.	Guidance changed to reflect this wording.
	2	2. You quote evidence on better tolerability of methylphenidate and mixed amphetamine salts. This is well known and clinicians in my office often do start with methylphenidate products. My concern is mixed amphetamine salts are not listed in concluding paragraph as recommend treatment for children. They are FDA approved and equally effective. Many patients tolerate them better so the availability of the option needs to be clear. My concern is medical directors would interpret the concluding paragraph to imply that only methylphenidate was recommended pharmacologic treatment.	The summary paragraph only lists MPH and atomoxetine because those are the only two agents that the evidence source determined to have a low strength of evidence for long-term (>12 mo) effectiveness. The evidence source states "many researchers and clinicians assume all psychostimulants are effective and safe for extended periods of time. The documentation for this assertion is not yet robust." The only medication for which there is evidence of poorer tolerability was guanfacine. There were no comparative long-term studies of MAS to another stimulant included in the review.
	3	3. I agree that behavior support should be first line for children prior to 6 years old. Unfortunately this service is lacking in most communities and even when available is difficult to access. A statement stating something to the effect of "if behavior therapy is unavailable for a patient or is ineffective in reaching patient and family goals, then medications should be considered." would be helpful.	According to comment #6 and #7, OPEC provides parenting education throughout much of the state.
<i>Health Plan Medical Director</i> Coos Bay, OR	4	Thanks for an excellent review. When you reviewed the evidence, did you find any evidence for doses of stimulants above the package insert recommended doses? We frequently see requests for escalating doses, yet some of my resources say there is little evidence for improvement over, for example, 30mg of Adderall XR. If there is good evidence to support escalating doses (or not escalation doses), that would be useful new clinical information for us to take to our physicians. Thanks again for your work.	For the most part, dosages were not specified in the evidence source. When they were, the highest noted dose for MPH was 54mg, for MAS was 30 mg, for atomoxetine was 2.0 mg/kg/day, for guanfacine was 4 mg/day. Table of included medications and FDA approved doses added to the guidance.

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Public Comments

Stakeholder	#	Comment	Disposition
<i>Physician</i> Bend, Oregon	5	<p>The HERC coverage guidelines are fairly complete regarding stimulant treatment of ADHD. The guidelines do not discuss comorbid conditions and the complexity they add to treatment. Additionally, the need for school communication to obtain information on diagnosis and assess treatment is not mentioned. Frequency of follow up is also important, especially regarding monitoring and record keeping to modify treatment as needed.</p> <p>We could tie up treatment recommendations including parent training and comorbidity and expand the resources available to an interested clinician by including the American Academy of Pediatrics 2011 revised guidelines: http://pediatrics.aappublications.org/content/early/2011/10/14/peds.2011-2654.full.pdf and the 2007 American Academy of Child and Adolescent Psychiatry recommendations: http://www.aacap.org/galleries/PracticeParameters/JAACAP_ADHD_2007.pdf</p> <p>In their present form, the HERC ADHD treatment guidelines add too little to clinicians' knowledge to be helpful.</p>	<p>The guidance document is a derivative product that is based on the AHRQ systematic review of the evidence. It is not intended to serve as a practice guideline, but as a recommendation for coverage. Thank you for providing these references. They do not conflict with the coverage guidance statements.</p>
<i>Outreach Coordinator</i> Corvallis, OR	6	<p>It is heartening to see the potential of parenting education included in the coverage for families who have young children diagnosed with ADHD in the HERC draft coverage document. Research has shown that effective early parenting contributes to later development of cognitive and social skills, positive peer relationships, and prevention of delinquency, risky behaviors, and school failure. Research also indicates that differences in parenting practices account for up to 50 percent of the gaps in school readiness. Effective parenting education programs have been linked with decreased rates of child abuse and neglect, better physical, cognitive and emotional development in children, increased parental knowledge of child development and parenting skills, improved parent-child communication, reduced youth substance abuse, and more effective parental monitoring and discipline. Of the parenting education programs suggested in the HERC document, The Incredible Years is the most widely used in Oregon. The program would be easily accessible to parents throughout the state, including rural areas.</p>	<p>Thank you for your comment.</p>
	7	<p>There are many organizations and agencies throughout the state that offer parenting education. There is not an umbrella agency in Oregon with the responsibility of overseeing the broad implementation of parenting education in the state. Therefore, it is difficult to generalize about the quality of implementation by all organizations. Oregon State University has been working for several years to evaluate and provide technical assistance to grantees funded by private foundations to provide parenting education programs in their local communities. The newest initiative is the Oregon Parenting Education Collaborative (OPEC). OPEC is a partnership between four of Oregon's largest foundations (The Oregon Community Foundation, The Ford Family Foundation, the Meyer Memorial Trust and The Collins Foundation) and Oregon State University (OSU). In addition to funding, OPEC supports grantees through evaluation, technical assistance, and professional development led by OSU. This is a multi-year grant program to support the delivery of evidence-based parenting education programs, increase access for parents to quality programs and to</p>	<p>Thank you for providing this information.</p>

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		provide leadership in coordinating existing programs within their regions. OPEC has created eleven parenting education “Hubs” that reach 19 of 36 Oregon counties. (The vision is that by 2020, the initiative would be statewide.) Grantees are held to a high degree of accountability in their delivery of evidence-based programs. All facilitators must be trained by a professional trainer representing the curricula and implemented in the recommended manner. In addition, all OPEC Hubs are extensively evaluated. Outcomes are available for individual parents, as well as for the system. For information about the OPEC initiative, visit http://www.oregoncf.org/receive/grants/grant-opportunities/ready-to-learn/parent-ed-collaborative . This webpage also has links to the OPEC First Year Report, A Snapshot of Parenting Education in Oregon, and What We Know about Parenting Education.	
	8	I believe that there is great potential for community-based organizations to meet the needs of parenting education as proposed by HERC. Many of them are prepared to fill the need immediately. If you would like more information about the evaluation we have been conducting or about OPEC, please let me know.	Thank you for your comment.
Lilly Indianapolis, IN	9	HERC has requested public comment on its draft coverage guidance on the treatment of ADHD. On page 6 of the guidance, overall summary states: ¹ “There is evidence to support the long-term effectiveness of both methylphenidate and atomoxetine for improving ADHD symptoms, as well as methylphenidate combined with psychosocial interventions, in children age six and over.” ¹ However, the guidance does not recommend atomoxetine. ¹ Lilly is submitting the following evidence as supplementary support for the recommendation of atomoxetine as another first-line treatment option for ADHD.	The guidance recommends “psychostimulant medication.” While it is understood that atomoxetine is not a true stimulant, some resources refer to it as a psychostimulant. Wording changed to “pharmacotherapy,” limited to medications with FDA approval to treat ADHD.
	10	“For a decade, Oregon has led the nation in methamphetamine-treatment admissions per 100,000 people; treatment admissions for methamphetamine are second only to those for alcohol...Although many people believe those addicted to methamphetamine do not recover, their rate of recovery is about the same as that for people addicted to cocaine, heroin and other stimulants.” ² Atomoxetine has not shown a pattern of response that suggests stimulant or euphoric properties. ^{3-4,13} Furthermore, clinical study data in over 2000 children, adolescents, and adults with ADHD and over 1200 adults with depression showed only isolated incidents of drug diversion or inappropriate self-administration associated with atomoxetine. ¹³	Thank you for this information.
	11	The review did not take into account evidence-based guidelines, which HERC considers as high-medium quality evidence. ⁵ Atomoxetine use has been discussed in various guidelines. AACAP (2007) ⁶ treatment guidelines suggest “an initial treatment plan that includes atomoxetine, amphetamine or methylphenidate preparations.” ⁶ The guidelines state atomoxetine “may be considered as the first medication for ADHD in persons with an active substance abuse problem, comorbid anxiety, or tics.” ⁶ Atomoxetine is preferred in patients who experience severe side effects to stimulants, such as mood lability or tics. ⁶ CADDRA (2011) ⁷ lists atomoxetine as a first-line agent for ADHD. ⁷ The guidelines state that atomoxetine may be particularly useful to ADHD patients with tic spectrum disorders or comorbid anxiety, and resistance and/or side effects	Thank you for providing these references. AACAP guideline states, “Direct comparisons of the efficacy of atomoxetine with that of MPH and amphetamine have shown a greater treatment effect of the stimulants.” CADDRA is the Canadian ADHD Resource Alliance. EbGS does not base their

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		to stimulant medications, including problems with worsening of sleep. ⁷ NICE (2008) ⁸ recommends that healthcare professionals should consider methylphenidate or atomoxetine when tics, Tourette’s syndrome, anxiety disorder, stimulant misuse, or risk of stimulant diversion are present. ⁸ Among FDA-approved non-stimulant agents, AAP (2011) ⁹ ranks the level of evidence for the treatment of elementary school-aged children (6-11 years of age) in the order of atomoxetine, followed by extended-release guanfacine, and extended-release clonidine. ⁹	decisions on the decisions of other guideline groups. Preferred treatment algorithms may be decided by other entities.
	12	Furthermore, the review only considered evidence up to May 2010. Since May 2010, additional evidence has been published supporting comparable efficacy for atomoxetine vs. methylphenidate in children/adolescents with ADHD (Please see attached publications for details). ¹⁰⁻¹²	Preferred treatment algorithms may be decided by other entities. Hanwella: meta-analysis of 9 RCTs of atomoxetine vs. MPH, longest trial was 12 weeks. Found no difference in efficacy, response rate or acceptability (measured by all-cause discontinuation). On subgroup analysis, MPH OROS was more efficacious than atomoxetine, although immediate release MPH was not. Hazell: meta-analysis of 7 RCTs of atomoxetine vs. MPH, longest trial was 10 weeks. Found similar response rates. van Wyk: meta-analysis 7 RCTs of atomoxetine vs. MPH, longest trial was 10 weeks. Found similar response to treatment, overall, and in patients with ODD. Response based on subtype (hyperactive, inattentive) also showed no difference.
	13	In closing, atomoxetine’s value summary is: <ul style="list-style-type: none"> • Atomoxetine offers continuous efficacy and has been proven effective in both hyperactive/impulsive and inattentive symptoms of ADHD. • Atomoxetine provides long-term control of ADHD symptoms with proven maintenance treatment in children/adolescents. • Atomoxetine is not a scheduled substance.¹³ • Atomoxetine does not worsen anxiety or tics in patients with ADHD and co-existing Tourette’s disorder or anxiety disorders.¹³⁻¹⁵ 	EbGS does not dispute the efficacy and safety of atomoxetine and other FDA approved medications for ADHD.

HERC Coverage Guidance – Treatment of Attention Deficit Hyperactivity Disorder Disposition of Public Comments

Stakeholder	#	Comment	Disposition
		Proven safety and tolerability profile in children, adolescents, and adults.	
	14	<p><u>Safety and Tolerability</u> Please see full prescribing information for complete safety information.</p> <ul style="list-style-type: none"> • Strattera (atomoxetine) contains a black box warning about an increased risk for suicidal ideation in children and adolescents with ADHD; therefore, anyone considering the use of Strattera in a child or adolescent must balance this risk with the clinical need. All pediatric patients who are started on therapy should be monitored closely for suicidality (suicidal thinking and behavior), clinical worsening, or unusual changes in behavior, especially during the initial few months of drug therapy or at times of dose changes, either increases or decreases.¹³ Families and caregivers should be advised of the need for close observation and communication with the prescriber.¹³ Strattera is approved for ADHD in pediatric and adult patients.¹³ Strattera is not approved for major depressive disorder.¹³ Pooled analyses of short-term (6 to 18 weeks) placebo-controlled trials of Strattera in children and adolescents (a total of 12 trials involving over 2200 patients, including 11 trials in ADHD and 1 trial in enuresis) have revealed a greater risk of suicidal ideation early during treatment in those receiving Strattera compared to placebo.¹³ The average risk of suicidal ideation in patients receiving Strattera was 0.4% (5/1357 patients), compared to none in placebo-treated patients (851 patients).¹³ No suicides occurred in these trials. A similar analysis in adult patients treated with Strattera for either ADHD or major depressive disorder (MDD) did not reveal an increased risk of suicidal ideation or behavior associated with the use of Strattera.¹³ • Strattera is contraindicated in patients known to be hypersensitive to Strattera or other constituents of the product, and in patients with narrow angle glaucoma, pheochromocytoma or a history of pheochromocytoma, or severe cardiovascular disorders.¹³ • Strattera should not be taken with a Monoamine Oxidase Inhibitor (MAOI) or within 14 days after discontinuing an MAOI or other drugs that affect brain monoamine concentrations.¹³ • Strattera can cause severe liver injury and should be discontinued and not restarted in patients with jaundice or laboratory evidence of liver injury.¹³ • Strattera should not be used in patients with severe cardiovascular disorders whose condition would be expected to deteriorate if they experience increases in blood pressure or heart rate that could be clinically important (e.g., 15 to 20 mm Hg in blood pressure or 20 beats per minute in heart rate).¹³ Strattera should be used with caution in patients whose underlying medical conditions could be worsened by increases in blood pressure or heart rate such as certain patients with hypertension, tachycardia, or cardiovascular or cerebrovascular disease.¹³ Pulse and blood pressure should be measured at baseline, following Strattera dose increases, and periodically while on therapy to detect possible clinically important increases.¹³ 	Thank you for this information.

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Stakeholder	#	Comment	Disposition
		<ul style="list-style-type: none"> <li data-bbox="338 264 1482 391">• Strattera at usual doses can cause treatment emergent psychotic or manic symptoms, e.g., hallucinations, delusional thinking, or mania in children and adolescents without a prior history of psychotic illness or mania.¹³ Discontinuation of treatment with Strattera should be considered if such symptoms occur.¹³ <li data-bbox="338 391 1461 423">• Other potentially serious side effects include slowing of growth, priapism, and difficulty urinating.¹³ 	