

MINUTES

Health Technology Assessment Subcommittee

Clackamas Community College
Wilsonville Training Center, Room 210
29353 SW Town Center Loop E
Wilsonville, Oregon 97070
December 10, 2015
1:00-4:00pm

Members Present: Som Saha, MD, MPH (Chair Pro Tempore); Chris Labhart; Gerald Ahmann, MD; Leda Garside, RN, MBA; Jim MacKay, MD (left at 3:40). Derrick Sorweide, DO (arrived 2:05)

Members Absent: Tim Keenen, MD, Mark Bradshaw, MD

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Adam Obley, MD, Val King MD, MPH & Craig Mosbaek (OHSU Center for Evidence-based Policy), Amber Stifter (Medtronic), Joe Badolato, DO (FamilyCare), Valerie Halpin, MD (Legacy), Bruce Wolfe, MD (OHSU), Rene Taylor (DexCom).

1. CALL TO ORDER

Saha called the meeting to order at 1 p.m.

2. MINUTES REVIEW

Minutes from the September, 2015 meeting were reviewed and approved 6-0.

3. STAFF REPORT

Coffman noted that the topic of Vertebroplasty, Sacroplasty and Kyphoplasty was inadvertently omitted from the public notice for this meeting. The rescan of this topic will come to a future meeting.

4. REVIEW NEED FOR UPDATES ON COVERAGE GUIDANCES APPROVED IN 2013

Obley reviewed the results of the rescan for Continuous Glucose Monitoring provided in the meeting packet. Livingston said she recommends an update as there are randomized trials with mixed evidence. There are also implementation concerns about the duration and indications for these devices. Som said in a rescan, we'd only want to take up a topic if the evidence is likely to change the recommendation. Obley said there are two reasons to consider an update. First, the new randomized trial is the largest and best-conducted to date. In addition, these devices are now being paired with insulin pumps, which is a novel use of the device.

Saha invited public comment.

Joe Badolato from FamilyCare testified that the evidence is mixed for this very expensive device. It is difficult to know when to start, when to stop use and for how long to continue use. He gave the example of a newly-diagnosed 8-year-old Type 1 diabetes patient who would qualify under the HERC guideline, but her HbA1c was barely over the limit after a short course of management without the device. Families are demanding the device and hoping for better control, but the evidence of significant benefit is lacking. In addition, the requirement for considering insulin pump therapy causes difficulty as the continuous monitors are usually prescribed before therapy. He said that these devices are being pushed by Byram and Medtronic representatives. He expressed surprise that HERC approved the current guideline based on limited evidence. In addition he said that determining compliance with previous treatment is difficult, as compliance isn't defined. He requested additional clarity from the next review.

Rene Taylor, a diabetes educator with DexCom, a manufacturer, also testified, requesting additional clarity around the requirement related to insulin pumps being considered or utilized. Consideration is not often documented in progress notes, and this is limiting access. There are devices approved for children as young as two years old, which are shown to reduce hypoglycemia in this vulnerable population. In addition, the evidence shows equivalence for the device with insulin injections or an insulin pump so the requirement for an insulin pump is not consistent with the evidence.

Staff noted an edit to the previously approved scope statement, adding mention that diabetes-related hospitalizations and emergency department visits were excluded as outcomes.

After brief additional discussion, the subcommittee voted 6-0 (Sorweide absent) to recommend the development of a new coverage guidance on the topic.

For Self Monitoring of Blood Glucose, Obley reviewed the rescanning summary. The reviews all suggested small improvements in HbA1c, but evidence is lacking on direct outcomes. Livingston said she doesn't believe this evidence has the potential to change the existing coverage guidance. The subcommittee voted 6-0 (Sorweide absent) to defer consideration of a new coverage guidance for this topic until the next two-year review cycle.

Obley reviewed the rescan for MRI for Breast Cancer. Livingston recommended not updating the current coverage guidance. The subcommittee voted 6-0 (Sorweide absent) to defer consideration of a new coverage guidance for this topic until the next two-year review cycle.

Obley reviewed the rescan for PET for Breast Cancer after initial diagnosis. Livingston recommended not updating the current coverage guidance. The subcommittee voted 6-0 (Sorweide absent) to defer consideration of a new coverage guidance for this topic until the next two-year review cycle.

Obley reviewed the rescan for Diagnosis of Obstructive Sleep Apnea. Livingston recommended the subcommittee consider updating the current coverage guidance in light of new evidence for home testing devices. The HERC may wish to address clinical pathways to reduce costs for diagnosis for sleep apnea. Livingston said that the recommendation wouldn't be likely to change but there could be recommendations to optimize efficient utilization of these tests. OHP medical directors have requested review. After brief additional discussion, the subcommittee voted 6-0 (Sorweide absent) to recommend the development of a new coverage guidance on the topic.

5. SCOPE DEFINITION: Hypofractionated Whole Breast Irradiation for Breast Cancer

Obley reviewed the scope statement, which was created with input from Samuel Wang, a radiation oncologist from OHSU and after public comment. He also reviewed the changes in response to public comments. Based on staff recommendation, the subcommittee members added gender in addition to age to Key Question 2, then approved the revised scope statement by a vote of 6-0.

6. METABOLIC AND BARIATRIC SURGERY

Coffman introduced Bruce Wolfe, the appointed expert for this topic. He is a retired bariatric surgeon, and also an investigator for research on a nerve stimulation device for treatment of obesity.

Obley reviewed the limitations on the evidence base as reviewed in the previous meeting as well as the newly-added evidence on reoperations. Livingston reviewed the GRADE-informed table and the box recommendations.

Saha noted that in this case values and preferences won't guide whether the procedures are conducted. Instead, society's values and preferences will guide the coverage decision; the variability in patient preferences can be decided by the patient. But society has values around diabetes prevention, the costs and risks of surgery. Ahmann suggested the language on page 30 of the coverage guidance expresses the issues very well. The subcommittee instructed Livingston to edit the values and preferences statements to reflect this before the guidance is posted for comment.

Discussion turned to the coverage recommendations themselves.

Under the first bullet for adult obese patients, the subcommittee removed the words "and <40" to avoid the perception that surgery would not be covered for adults with BMI of 40 or higher."

In addition, the subcommittee discussed the comorbidities other than diabetes which would qualify someone with a BMI of 35-40 for surgery. These are not strictly evidence-based though other payers cover the surgery for patients with varying numbers and types of comorbidities. Those listed in the meeting materials reflected many of the more common ones. Saha noted that we have evidence about hypertension, even though that's not as significant since hypertension has other treatment. Gingerich reviewed some grammatical differences between the last row of the GRADE table and the box and asked permission to align them for clarity. The subcommittee agreed to allow this and also decided to remove dyslipidemia from the list of comorbidities that would allow a person with BMI between 35 and 40 to have surgery, even though some other payers allow surgery for this comorbidity.

Wolfe argued for not specifying specific comorbidities, pointing out that psychosocial reasons have been considered indications. The subcommittee elected to retain its list of comorbidities as edited.

The subcommittee discussed requirements for support groups, surgeon volume and acceptable complication rate. Wolfe recommended that the subcommittee not create requirements based on the

limited evidence but instead require the surgery be provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program. It requires outcomes reporting, postoperative support groups and requires adequate surgeon and hospital volume. He said Medicare used to require this but no longer does, and that some private payers are beginning to adopt it. After discussion of the difficulty in evaluating some of the listed criteria, the subcommittee accepted Wolfe's recommendation. Accredited bariatric surgery programs are available in various regions of the state, mitigating the impact of the requirement on patients in many more rural areas, though Labhart expressed concern that Bend is the only program east of the Cascade Mountains. Saha said he doesn't believe anyone is trying to do bariatric surgeries in other parts of Eastern Oregon, but even if there were, the benefit of having surgery available locally would need to be balanced with the risks associated with a lower-volume center. Garside expressed concern that the subcommittee should evaluate the evidence with regard to these factors rather than limiting access based on an external entity, but others doubted that the HERC could monitor these factors as well as a dedicated group. Gingerich asked whether the accreditation includes outpatient surgery centers. Wolfe said there is a separate program for these facilities.

After discussion, the subcommittee removed the requirements that the surgery be performed by an experienced surgeon as well as the requirements for hospital surgical volume and specific postoperative groups and outcomes. These were replaced with a requirement (a weak recommendation) that the surgeries be performed in an accredited facility. Wolfe said that this accreditation would capture the intent of the subcommittee, but without the subcommittee having to stay up-to-date on the intricacies of the evolving evidence base on such requirements.

Livingston reviewed the GRADE table on surgery for children. Saha expressed doubt that waiting until age 18 would create irreversible harm. Wolfe said he didn't object to the summary statement, but referred to a recent study and suggested the subcommittee revisit this topic as well as surgery for BMI under 35 as new evidence becomes available. After discussion the subcommittee agreed not to recommend coverage of this surgery for children.

The subcommittee discussed the recommendation against coverage for complications. Wolfe said this would be problematic for patients with gastric bands which have a high failure rate and risk of severe complications. He noted that other payers separate band removal from other reoperations. Saha questioned whether band removal would be considered bariatric surgery. Wolfe said in some cases it would. Halpin said that other payers do get confused about this. Livingston asked what the indications for removal of a band are. Wolfe said that he will remove them if the patient wants them removed. You don't always know if they plan another surgery at that point. Halpin said there are also complications from bands and associated erosion and scar tissue. There is a risk of irreversible harm from leaving a band in. Wolfe said most payers cover the conversion of a band to a more complicated procedure (e.g. from lap band to sleeve gastrectomy or gastric bypass).

The subcommittee also discussed the issues around patients who convert to another bariatric surgery. Obley said there is low-certainty evidence that patients lose additional weight with these conversion surgeries, and also a higher complication rate. Obley said we don't have direct evidence about whether the benefits of conversion outweigh the harms from the higher complication rate. No data on the numbers of patients with bands are available for Oregon, but Wolfe said the number is much lower than it was a few years ago. Livingston said that access to bariatric surgery is limited as many providers only take on a limited number of Medicaid patients, and questioned whether patients undergoing an initial surgery should be given priority due to proven benefit. Garside noted we need to take into account the

costs of the complications of not having surgery. King suggested allowing accredited centers to make decisions for individual patients about reoperations.

Saha said there are different kinds of conversions—from band to sleeve gastrectomy or from sleeve gastrectomy to bypass or biliopancreatic diversion for example. Obley said there is evidence on these, but there is not much on conversion of gastric bypass to biliopancreatic diversion. He reviewed the weight loss for various conversion surgeries.

Garside asked about recommending against coverage for banding based on the failure rate. The group discussed this but didn't decide to make a change. Wolfe and Halpin said that bands aren't used much anymore because of the complications.

After further discussion, the subcommittee removed the clause recommending against coverage for reoperations based on evidence of additional weight loss, but left the GRADE table row on reoperations and additional evidence as a part of the coverage guidance. The GRADE table will contain a statement that the subcommittee makes no recommendation that coverage criteria for reoperations should be different from primary surgery. The rationale will be based on very low quality evidence that conversion surgeries are associated with increased complications as well as additional weight loss.

The subcommittee addressed recommending coverage for BMI of 30 to 35. There was no discussion and coverage was not recommended for this population.

The subcommittee voted 6-0 (MacKay absent) to post the draft coverage guidance for public comment, with the revisions made during the meeting as well as the additional edits made by staff at the subcommittee's request.

DRAFT HERC Coverage Guidance

Coverage of metabolic and bariatric surgery (including Roux-en-Y gastric bypass, gastric banding, and sleeve gastrectomy) is recommended for:

- Adult obese patients (BMI \geq 35) with
 - Type 2 diabetes (*strong recommendation*) OR
 - at least two of the following other serious obesity-related comorbidities: hypertension, coronary heart disease, mechanical arthropathy in major weight bearing joint, sleep apnea (*weak recommendation*)
- Adult obese patients (BMI \geq 40) (*strong recommendation*)

Metabolic and bariatric surgery is recommended for coverage in these populations only when provided in a facility accredited by the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (*weak recommendation*).

Metabolic and bariatric surgery is not recommended for coverage in:

- Patients with BMI $<$ 35, or 35-40 without the defined comorbid conditions above (*weak recommendation*)
- Children and adolescents (*weak recommendation*)

5. ADJOURNMENT

The meeting was adjourned at 3:45 pm. The next meeting is scheduled for February 18, 2016 from 1:00-4:00pm in Room 111-112 of the Wilsonville Training Center of Clackamas Community College.