

## MINUTES

Health Technology Assessment Subcommittee  
Meridian Park Community Health Education Center  
19300 SW 65th Avenue, Tualatin, OR  
September 24, 2012  
1:00-4:00pm

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**Members Present:** Alissa Craft, DO, MBA; Gerald Ahmann, MD; George Waldmann, MD; James MacKay, MD; Tim Keenen, MD.

**Members Absent:** Ed Toggert, MD.

**Staff Present:** Darren Coffman; Wally Shaffer, MD, MPH; Jason Gingerich.

**Also Attending:** Alison Little, MD (CEBP); Shannon Vandergriff (CEBP); Vinod Dasa<sup>1</sup> (Bioventus), Brad Bisson<sup>1</sup> (Depuy-Mitek), Russ Riggs<sup>1</sup> (Reflex Clinic), Joe Salmonese<sup>1</sup>, Ken Hirons<sup>1</sup>, Leonard Allen<sup>1</sup>, Chuck Martin<sup>1</sup>, Sherry Williams<sup>1</sup>, Greg Carroll<sup>1</sup> (Reflex Clinic), George M. Douglass<sup>1</sup>, Nancy Borden<sup>1</sup>, Bill McKee (Roche), Carolyn Walwyn (Slocum Orthopedics), Judy Fry (American Diabetes Association), Peter Heeckt (Bioventus), Dena Scearce (Medtronics), Michael Bolen (Medtronic), Jason Lerner (Depuy Synthes), Chris Arapoff (Medtronic), Denise Taray (DMAP), Ken Lozy (Bioventus), Cari Hayes (Medtronic), Michael Pfister (Interventional & Vascular Consultants), Margaret Eastman (Sanofi), Biji Joseph<sup>1</sup> (Sanofi), Abby Anderson (Bioventus), Chris Browner (Bioventus), Elise Brown (ADA), Rich Hatlin (Sanofi), Jake Thielen (Orthopedica & Fracture Clinic), Joanie Cosgrove (Medtronic), Nan Hein (Oregon Association of Orthopedists), Sean Galling (Ferring Pharmaceuticals), P. Cosgrove (Medtronic), Frances Lawson (Reflex Clinics), Mary Anderson<sup>1</sup> (Reflex Clinics), Alec Slebel (LHNW), Andrea Bruno (American Diabetes Association), Paul Nielsen (MedImmune)

<sup>1</sup>Testified on Viscosupplementation

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### 1. CALL TO ORDER

Alissa Craft called the meeting of the Health Technology Assessment Subcommittee (HTAS) to order at 1:00 pm. She introduced Tim Keenen, MD, a new member of the subcommittee, as well as Jason Gingerich who will serve as staff for this subcommittee.

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### 2. MINUTES REVIEW

No changes were made to the draft June 2012 minutes.

**Minutes approved 5-0.**

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### 3. REVIEW OF PUBLIC COMMENTS

#### A) Vertebroplasty, Sacroplasty, and Kyphoplasty

Alison Little reviewed the written public comments and the CEBP's recommended responses as outlined in the meeting materials. No revisions were suggested by the members.

Dr. Craft then invited verbal comments.

Jason Lehrer, from Depuy testified. He disclosed a conflict of interest by nature of his employment. He asked the subcommittee to consider the hierarchy of evidence, clinician experience and patient values. He expressed concerns about the NEJM studies, suggesting they be downgraded to the level of the other studies considered to be of lower quality.

Mike Pfister, is an interventional radiologist practicing in Oregon since the late 90's. He said he has performed vertebroplasty on 350 patients. Expressed agreement with Lehrer but disagreed with the proposed coverage guideline, especially the definition of routine. He believes the Medicare local coverage determination (LCD) will guide him without a more definitive definition of what routine/nonroutine means. Departing from LCD is a big effort which may not be necessary for this committee.

Discussion by the Subcommittee focused around the definition of routine and whether exceptions to the noncoverage decisions might be appropriate in certain cases.

A motion was made and seconded to accept the draft coverage guidance recommendation. **The motion carried 5-0**, and Craft requested that staff work on a definition of routine which can be forwarded to HERC for consideration during guideline development. The approved language is:

[HERC COVERAGE GUIDANCE](#)  
Vertebroplasty, kyphoplasty, and sacroplasty should not be covered for routine osteoporotic compression fractures.

#### B) Viscosupplementation for Osteoarthritis of the Knee

Alison Little reviewed the public comments and the CEBP's recommended responses. No revisions were suggested by the members. There was extensive discussion and public comment on this topic. Thirteen individuals representing patients, providers and product manufacturers gave public comment, all in support of coverage for this procedure.

Public comments focused on several areas:

- Personal testimonies from physicians and patients reporting successful viscosupplementation treatment and urging coverage of the procedure.

- Testimony raising concerns about the quality of the evidence used in the noncoverage determination. Concerns included inclusion of inappropriately selected patients in the studies as well as whether the size of the effect from treatment was significant.
- Testimony that analgesics are insufficient or contraindicated for some patients. Steroids have adverse effects. The only other alternative is knee replacement, which is more expensive and more invasive.
- Testimony arguing that fluoroscopic guidance may improve effectiveness.
- Testimony observing that other similar bodies and other payers have decided to cover the procedure.

Committee members discussed these comments, but also the potential for abuse, that some patients see no benefit or experience harm from these procedures, and that the evidence considered shows a benefit which may not be clinically significant. In addition, there was discussion of the difficulty of determining which patients may be good candidates, and that pain measurement is highly subjective. Several committee members stated that this is a difficult decision.

A motion was made to approve the draft coverage guidance as written and forward to HERC. **Motion approved 4-1 (Keenen)**. Coffman said that this will be taken to the next HERC meeting October 11 where there will be more limited opportunity for public comment. The approved language is:

[HERC COVERAGE GUIDANCE](#)  
 Viscosupplementation should not be covered for the treatment of pain associated with Osteoarthritis (OA) of the knee.

### C) Continuous Glucose Monitoring in Type II Diabetes

Alison Little reviewed the public comments and the CEbP's recommended responses. No revisions were suggested by the members. There was minimal discussion.

At committee request, the coverage guidance was changed to allow for retrospective glucose monitoring for Type 1 diabetes.

It was also noted that the revised draft guidance includes a noncoverage recommendation for real-time continuous glucose monitors for type 2 diabetes based on a new AHRQ report. Since this change was not a result of public comment, the revised guidance will be reposted for an additional 21-day public comment period.

A motion was made to approve the revisions to the draft coverage guidance as written and repost it for public comment. **Motion approved 5-0.**

### HERC COVERAGE GUIDANCE

Real-time continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus patients with HbA1c levels greater than 8.0% or a history of recurrent hypoglycemia, for whom insulin pump management is being considered, initiated, or utilized.

Real-time continuous glucose monitoring systems should not be covered for Type 2 diabetes mellitus patients.

Retrospective continuous glucose monitoring systems should be covered for Type 1 diabetes mellitus and should not be covered for Type 2 diabetes mellitus.

**The remaining guidances on MRI for breast cancer diagnosis and the diagnosis and treatment of sleep apnea in adults were not reviewed as the time allotted for the meeting had expired.**

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#### **4. COVERAGE GUIDANCE ALGORITHM**

This topic was not discussed due to insufficient time. Members were encouraged to send any comments via email to staff as the algorithm will be discussed at the October 11<sup>th</sup> HERC meeting.

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#### **5. REVIEW OF NEW DRAFT COVERAGE GUIDANCES**

A. Self-monitoring of Blood Glucose

This topic was not discussed due to insufficient time.

B. PET Scans for Breast Cancer

This topic was not discussed due to insufficient time.

C. Carotid Endarterectomy

This topic was not discussed due to insufficient time.

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#### **6. PUBLIC COMMENT**

No additional public comment was received at this time.

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#### **7. ADJOURNMENT**

The meeting was adjourned at 4:00 pm. The next meeting is scheduled for November 26, 2012 from 1:00-4:00pm in Room 117B of the Meridian Park Hospital Community Health Education Center in Tualatin.