Minutes

HEALTH EVIDENCE REVIEW COMMISSION
Meridian Park Hospital
Community Health Education Center Room 117B&C
Tualatin, OR 97062
August 9, 2012

Members Present: Alissa Craft, DO, MBA, Vice-Chair (Chair Pro-tem); Lisa Dodson, MD; James Tyack, DMD; Beth Westbrook, PsyD; Leda Garside, RN; Kathryn Weit; Mark Gibson; Wiley Chan, MD; Vern Saboe, DC.

Members Absent: Som Saha, MD, MPH, Chair; Irene Croswell, RPh; Gerald Ahmann, MD.

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

Also Attending: Denise Taray, DMAP; Alison Little, MD MPH, Shannon Vandegriff, and Erika Zoller, OHSU CeBP; Joanie Cosgrove, Medtronic; Neal Mills, ODS Health.

Call to Order

Alissa Craft, Vice-Chair of the Health Evidence Review Commission (HERC), called the meeting to order. Role was called.

Approval of Minutes

MOTION: To approve the minutes of the June 14, 2012 meeting as presented. CARRIES 9-0.

Director's Report

Regarding ICD-10-CM conversion, Darren Coffman reported that CMS is in the process of considering public comment they recently received and have indicated they will share their decision of when ICD-10-CM will be implemented by the end of summer; no definitive date for that decision has been set. (*Update: 8/27/12 HHS announces official one-year delay for ICD-10-CM implementation; new compliance date is October 1, 2014.)*

Staff distributed the Commission approved conflict of interest forms which need to be completed by each Commissioner and subcommittee member annually. Additionally, Dr. Cat Livingston stated that if any new conflicts arise during the year, a new COI form should be completed. Members are asked to return the completed forms via regular mail to OHPR/HERC, 1225 Ferry Street NE, Suite C, Salem, Oregon 97301.

Subcommittee Policies

Attendance and appointment to the subcommittees

A policy regarding subcommittee member's appointment and attendance was reviewed (meeting materials page 10). Coffman stated this policy was drafted in response to questions staff has needed to address, particularly in regards to attendance by subcommittee members. The HERC Bylaws do not address attendance apart from Commission members.

MOTION: To adopt the proposed policy with changes. Carries 9-0.

Acceptance of public written testimony

Due to the public interest and visibility of the work of this Commission, revisions to the current policy on written testimony were suggested and reviewed (meeting materials page 11).
This proposed change will clarify:

- when written comment can be received (not any time) for inclusion in a particular meeting
- acceptance of comments on topics being reviewed through the coverage guidance process, which are limited to a set 30-day comment window.

Members suggested creating a written Conflict of Interest (COI) statement for those testifying by clearly defining what constitutes a potential conflict and differentiating expert testimony vs. public comment. Staff will:

- craft a statement and ensure the document is available at both the meeting sign-in and the testimony tables
- clearly introduce invited guests when they are addressing the Commission
- ask individuals testifying or giving public comment to review the statement and declare any conflicts before speaking

Further, members suggesting adding headings to the proposed document to add clarity and to ensure the stated allotted testimony time frames are consistent.

MOTION: To adopt the proposed policy with the two clarifications discussed. Carries 9-0.

Subcommittee Reports

Value-based Benefits Subcommittee (VbBS) Report (HERC meeting materials page 30-111)

Ariel Smits, Cat Livingston and Lisa Dodson reported the VbBS had met earlier in the day, August 9th. Each helped to summarize a number of topics discussed.

Recommendations for the biennial list include:

- ICD-10-CM conversion recommendations (by specialty group):
    - o Orthopedics
    - o Sleep conditions

- o Hyperbaric oxygen
- o Dysfunction
- o Hematology
- o General surgery
- o Ophthamology

MOTION: To accept the ICD-10-CM VbBS recommendations as stated. See the VbBS minutes of 8/9/12 for a full description. Carries: 9-0.

Recommendations for interim changes, effective 10/1/12 include:

- Adjusting the Prioritized List into compliance with the previously HERC-approved coverage guidances (VbBS meeting materials pages 22-42). Topics include:
  - o Planned Cesarean Delivery
  - o Elective Induction of Labor
    - o Wording clarified to show elective induction of labor should not be covered for fetal macrosomia at any gestational age, and for breech presentation as a separate condition.
  - o Routine Ultrasound in Pregnancy
  - o MRI for Breast Cancer Screening
  - o Knee Arthroscopy for Osteoarthritis
  - o Hip Resurfacing
    - ▪ Language edited to replace the phrase "a covered service" with "included on this line."
- Edit the Enzyme Replacement Therapy guideline note to include line 264-Glycogenosis, allow coverage of therapy for infantile Pompe's disease on line 264 and to clarify all other enzyme replacement therapies are included on Line 684-Endocrine and Metabolic Conditions with No or Minimally Effective Treatments or No Treatment Necessary.

Two additional topics that time did not allow for discussion at the VbBS meeting were presented for the Commission's consideration: Recommendations for changes involving the biennial (10/1/12) Prioritized List:

- Edit the new severe inflammatory skin disease guideline to read:
  Biologics are ~~only~~ covered on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.
- Rename line 197 CANCER OF BREAST; AT HIGH RISK OF BREAST CANCER and delete all line 4 references.

MOTION: To accept the VbBS recommendations as stated, including the modifications to the coverage guidances on Elective Induction of Labor and Hip Resurfacing. Carries: 9-0.

Additional Discussion:

Dodson reported there was considerable discussion about several issues that relate to spine or back pain.

- The coverage guidance for Low Back Pain-Pharmacologic Interventions was not incorporated because the List prioritizes condition/treatment pairing, not medications. Further, uncomplicated back pain is prioritized so low it is not in or near the funded region.

- The coverage guidance for Lumbar Discography was not incorporated because that condition is already excluded from coverage.
- The coverage guidances for Low Back Pain Non-Pharmacologic Interventions and Artificial Disk Replacement require further study and are scheduled to be reviewed in October.

Detailed information may be found in the VbBS Minutes.

Biennial List

Coffman reviewed the Draft 2014-15 Prioritized List of Health Services (pages 112-153) line structure, pointing out that this version of the List includes all changes approved through June, 2012, but not modifications approved today. The intensive review of the past year saw many lines merged, resulting in a 20-line shorter List. Though the number of lines is shorter, recent waiver negotiations with CMS resulted in an agreement to retain the current funding line's relative position for the next five years.

One major change mentioned involved two lines previously hand-adjusted so that they would appear in the top 12 as part of the "Healthy Dozen." These two lines (Obesity/Intensive Counseling and Hypertension and Hypertensive Disease) were re-ranked according to their actual formula scoring, which resulted in them being prioritized lower on the list.

MOTION: To approve the Draft 2014-15 Prioritized List of Health Service, including changes resulting from today's VbBS report. Carries: 9-0.

Health Technology Assessment Subcommittee (HTAS) Report

Wally Shaffer explained there are three coverage guidances from this subcommittee being proposed today (overview of the three available in the meeting materials on pages 158-167).

HTAS Coverage Guidance Recommendations:

- **Artificial Disc Replacement** (page 168)
  The 30-day public comment period on the draft guideline closed May 30, 2012. Public comments were received and considered. This technology is an alternative to spinal fusion and is clinically comparable. Lumbar or cervical artificial disc replacement (ADR) should be a covered service only when certain criteria are met. See guidance for specific details.

  For lumbar discography, members discussed adopting additional language "for chronic low back pain due to degenerative disk disease." The guideline stipulates patients must meet FDA approved indications, which are defined in the guidance on page 173, including the language: *Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.*

  Approved Coverage Guidance:

  Artificial disk replacement should be a covered service only when all of the following criteria are met:

  Lumbar artificial disc replacement

1) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
2) Patients must be 60 years or under;
3) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
    - Failure of at least six months of conservative treatment
    - Skeletally mature patient
    - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

1) Patients must meet FDA approved indications for use and not have any contra-indications. FDA approval is device specific but includes:
    - Skeletally mature patient
    - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

MOTION: To approve the proposed coverage guidance for artificial disk replacement. Carries 9-0.

- **Lumbar Discography** (page 181)
  The 30-day public comment period on the draft guideline closed May 30, 2012. Evidence is insufficient to permit conclusions about the reliability of discography or its ability to predict outcomes in patients with chronic low back pain and uncomplicated lumbar degenerative disc disease who are candidates for spinal fusion. The subcommittee recommends against coverage of lumbar discography.

  Approved Coverage Guidance:
  Lumbar discography should not be a covered service for patients with low back pain and uncomplicated lumbar degenerative disc disease.

MOTION: To approve the proposed coverage guidance for lumbar discography. Carries 9-0.

- **Hip Resurfacing** (page 189)
  The 30-day public comment period on the draft guideline closed May 30, 2012. This is considered an alternative to hip replacement with comparable short term effectiveness. The subcommittee recommends coverage under certain criteria.

  Approved Coverage Guidance:
  Hip resurfacing should be a covered service for patients who are likely to outlive a traditional prosthesis and who would otherwise require a total hip replacement, and should only be done by surgeons with specific training in this technique.

  The following criteria should be required:
  - Diagnosis of osteoarthritis or inflammatory arthritis;
  - Individual has failed nonsurgical management; and

- The device is FDA approved.

Patients who are candidates for hip resurfacing must not have FDA contraindications including:

- Patients with active or suspected infection in or around the hip joint, or sepsis
- Patients who are skeletally immature
- Patients with any vascular insufficiency, muscular atrophy, or neuromuscular disease severe enough to compromise implant stability or postoperative recovery
- Patients with bone stock inadequate to support the device, including severe osteopenia or a family history of severe osteoporosis or osteopenia
- Patients with osteonecrosis or avascular necrosis with >50% involvement of the femoral head
- Patients with multiple cysts of the femoral head
- Females of childbearing age
- Patients with known moderate-to-severe renal insufficiency
- Patients who are immunosuppressed with diseases such as AIDS or persons receiving high doses of corticosteroids
- Patients who are severely overweight
- Patients with known or suspected metal sensitivity

MOTION: To approve the proposed coverage guidance for hip resurfacing. Carries 9-0.

Evidence-based Guidelines Subcommittee (EbGS) Report

Wiley Chan, EbGS Chair, and Livingston explained there are five coverage guidances being proposed today (overview of the five available in the meeting materials on pages 207-222).

- **Advanced Imaging for Low Back Pain** (page 226)
  The 30-day public comment period on the draft guideline closed June 9, 2012. Imaging should not be covered for patients with non-specific low back pain who do not present with certain red flag conditions such as suspected spinal column infection, compression fracture, nerve compression disorders (complete list). See guidance for specific details.

  Approved Coverage Guidance
  In patients with non-specific low back pain and an absence of "red flag" conditions:
  1) imaging (e.g. x-ray, CT, or MRI) should not be covered, and
  2) thermography and surface electromyography should not be covered.

  If patients have persistent (> 1 month) low back pain and signs or symptoms of radiculopathy or spinal stenosis, appropriate imaging should be covered (MRI preferred, CT second choice) **only if** the patient is a potential candidate for surgery or epidural steroid injection (for suspected radiculopathy).
  If patients have severe or progressive neurologic deficits, or clinicians suspect a serious underlying condition (e.g. cancer or infection), prompt workup with MRI (first choice) or CT should be covered.

MOTION: To approve the proposed coverage guidance for advanced imaging for low back pain. Carries 9-0.

- **Nonpharmacologic Interventions for Treatment Resistant Depression** (page 235)
  The 30-day public comment period on the draft guideline closed July 18, 2012. This coverage guidance does not speak to initial therapy, which may include pharmacologic treatment and/or psychotherapy.

  The subcommittee recommends coverage of psychotherapy, repetitive transcranial magnetic stimulation and electroconvulsive therapy under certain circumstances, but recommends noncoverage for vagus nerve stimulation.

  Approved Coverage Guidance
  In patients with an episode of major depressive disorder who have failed an initial trial of antidepressants, psychotherapy should be covered.
  In patients with an episode of major depressive disorder who have failed at least two or more pharmacologic treatments the following treatments should be covered:
  1) Repetitive transcranial magnetic stimulation
  2) Electroconvulsive therapy

  Vagus nerve stimulation should not be covered.

MOTION: To approve the proposed coverage guidance for nonpharmacologic interventions for treatment resistant depression. Carries 9-0.

- **Neuroimaging in Dementia** (page 256)
  The 30-day public comment period on the draft guideline closed July 18, 2012. No comments were received. Though dementia is potentially reversible, clinical prediction rules aimed at identifying patients for whom neuroimaging would result in a changed diagnosis have a high rate of error (both false negative and positive). Further, generally there is no evidence of improved outcomes from any neuroimaging intervention other than detecting causes of reversible dementia. Though structural neuroimaging should be covered to rule out reversible causes of dementia such as tumors, but do not include cerebral ischemial or infarcts.

  Approved Coverage Guidance
  Screening of asymptomatic patients for dementia with neuroimaging should not be covered.
  Structural neuroimaging should be covered to rule out reversible causes of dementia.*
  In patients with mild cognitive impairment, imaging should not be used to predict progression of the risk of developing dementia.
  Functional neuroimaging (PET, SPECT or fMRI) should not be covered for screening, diagnosis, or monitoring of dementia.

MOTION: To approve the proposed coverage guidance for neuroimaging in dementia. Carries 9-0.

- **Neuroimaging in Headache** (page 266)
  The 30-day public comment period on the draft guideline closed July 18, 2012. The subcommittee recommends noncoverage of neuroimaging (CT or MRI) patients presenting with a variation of usual headache symptoms. For patients with a clear history of migraine, neuroimaging should not be covered unless certain red flag

conditions are present, including thunderclap headache, focal neurologic symptoms, change in headache frequency, characteristics or associated symptoms, abnormal neurological examination, neck stiffness, or cluster headache. (complete list).

Approved Coverage Guidance
In patients who present with a variation of their usual headache (e.g. more severe, longer in duration, or not responding to drugs), CT or MRI should not be covered. Neuroimaging (CT or MRI) should not be covered for those with a clear history of migraine, unless a red flag* is present.

MOTION: To approve the proposed coverage guidance for neuroimaging in headache. Carries 9-0.

- **Hip Surgery Procedures for Femoroacetabular Impingement Syndrome (FAI)** (page 275)
  The 30-day public comment period on the draft guideline closed May 22, 2012. There were many public comments offered on this topic. The subcommittee reviewed the evidence from two trusted sources which came to differing conclusions, though there appears to be insufficient for proof of efficacy. FAI surgery, however, is widely practiced and there are no clear alternative therapies. The subcommittee recommends this topic be tabled with no formal recommendation. See meeting materials for specific details.

Additional Discussion

Discussion ensued on how and if they should make statements and policies about treatments, such as FAI surgery, where the evidence is unclear or insufficient. Coffman pointed out most standard treatments actually do not have formal evidence to support their efficacy, though standard of care alone should not guide a coverage decision. A complicating factor for this condition is that FAI is a set of symptoms, rather than a clear disease, illness or medical condition; in fact there is no diagnostic code. Commercial insurers are covering its treatment.

EbGS members are discussing decision-making principles for determining coverage guidances and are developing an algorithm for navigating issues such as trusted sources conflicts, community standard of care which may not be supported by evidence and areas of insufficient evidence. The draft policy is scheduled to be reviewed in the near future.

Gibson suggested amending the guidance, resulting in the following **Approved Coverage Guidance**:

The Evidence-based Guidelines Subcommittee reviewed the evidence which was found to be insufficient for proof of efficacy. The challenges faced by the subcommittee were exacerbated by the fact that there are no clear diagnostic parameters to define the condition.

MOTION: To adopt the coverage guidance for FAI surgery as amended which acts to table a definitive decision. Carries 9-0.

Prioritization Review and Next Topics

Livingston briefly reviewed the prioritized topics for EbGS and HTAS, which was emailed to all members prior to the meeting (page 286).

MOTION: To approve the prioritization methodology and topics as written. Carries 9-0.

Public Comment

There was no public comment at this time.

Adjournment

Meeting was adjourned at 5:07 pm. Next meeting will be from 2:00-5:00 pm on Thursday, October 11, 2012 at the Meridian Park Hospital Health Education Center in Conf. Room 117 B&C.