Health Technology Clinical Committee
Date: December 10th, 2010
Time: 8:00 am – 2:30 pm
Location: Marriott Hotel – 3201 South 176th Street, Seattle, WA 98188
Teleconference Bridge: 1-877-597-2663 Access Code: 5855297
Adopted: March 18th, 2011

HTCC MINUTES

Members Present: Dr. Brian Budenholzer; Dr. Carson Odegard; Dr. Richard Phillips; Dr. Craige Blackmore; Dr. Marie-Annette Brown; Dr. Kevin Walsh; Dr. Christopher Standaert; Michelle Simon; Dr. Michael Souter and Megan Morris.

Absent: Dr. Michael Myint

HTCC FORMAL ACTION

1. **Call to Order**: Dr. Budenholzer, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **October 22nd, 2010 Meeting Minutes**: Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.
   - *Action: Seven committee members approved the October 22nd, 2010 meeting minutes. Two committee members abstained from voting. Amended with editorial changes.*
3. **Total Knee Arthroplasty (TKA) draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The Total Knee Arthroplasty findings & decision was approved and adopted by the committee.
   - *Action: Seven committee members approved the Total Knee Arthroplasty findings & decision document. Two committee members abstained from voting.*
4. **Routine Ultrasound (US) draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The Routine Ultrasound findings & decision was approved and adopted by the committee.
   - *Action: Seven committee members approved the Routine Ultrasound findings & decision document. Two committee members abstained from voting.*
5. **Vertebroplasty, Kyphoplasty and Sacroplasty:** The HTCC reviewed and considered the Vertebroplasty, Kyphoplasty and Sacroplasty technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, the public and agency medical directors and an invited clinical expert. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Vertebroplasty	**10**	0	0
Kyphoplasty	**10**	0	0
Sacroplasty	**10**	0	0

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Vertebroplasty, Kyphoplasty and Sacroplasty surgical techniques reflective of the majority vote.

SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Introductions

- ✓ The Health Technology Clinical Committee (HTCC) met on December 10th, 2010.

Agenda Item: Meeting Open and HTA Program Update

Dr. Brian Budenholzer, HTCC Chair, opened the public meeting.

- ✓ Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics and introductions.

Agenda Item: Previous Meeting Business

October 22nd, 2010 Meeting Minutes: Chair referred members to the draft minutes and called for a motion and discussion. Minutes were circulated prior to the meeting and posted.

- *Action: Seven committee members approved the October 22nd, 2010 meeting minutes. Two committee members abstained from voting. Amended with editorial changes.*

Total Knee Arthroplasty (TKA) Findings and Decision: Chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. Two public comments were received and were included in the committee meeting packets.

- *Action: Seven committee members approved the Total Knee Arthroplasty (TKA) findings & decision document. Two committee members abstained from voting.*

Routine Ultrasound (US) Findings and Decision: Chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. No public comments were received.

- *Action: Seven committee members approved the Routine Ultrasound (US) findings & decision document. Two committee members abstained from voting. Amended with editorial changes.*

Agenda Item: HTA Program Review

- Leah Hole-Curry, HTA Program Director, provided the HTA context for the meeting and an update on program activities including:
  - Leadership acknowledgement and change. Dr. Brian Budenholzer has resigned as the HTCC Chair due to accepting an out of state professional opportunity. Dr. Craige Blackmore has accepted the role as chair of the HTCC.
  - State purchasing context and budget reductions and reform efforts, medical technology is driver of increased medical costs and has quality gaps.
  - HTA is designed to use reliable science and independent committee to get best information on what works, what is safe and what provides value.
  - HTA outcomes include transparency; reports and articles reviewed; and coverage decisions made.

- Comparison with private industry and Medicare decisions completed.
- Program has received recent recognition from public media, clinical press, and various medical and health policy groups with either story highlights or invited presentations.

Agenda Item: Vertebroplasty, Kyphoplasty and Sacroplasty Topic Review

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Staff provided an overview of the timeline and referred HTCC members to the included key questions and population of interest for Vertebroplasty, Kyphoplasty and Sacroplasty review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Brian Drew an orthopedic surgeon from Ontario, Canada. Dr. Drew completed a conflict of interest and indicated no conflicts.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: Six stakeholders scheduled time for public comments.
  - Dr. Evert Verschuyl, arranged by Medtronic. Urged coverage; quality of life key for elder patient; alternatives ineffective; felt several guidelines omitted from report.
  - Dr. Neil Shonnard, arranged by Medtronic. Urged coverage for kyphoplasty; believes that this procedure relieves pain and improves function; obtain quality data through registry function such as SCOAP.
  - Dr. Kenneth Symington, Society of Interventional Radiology (SIR), urged coverage, premature to deny, his experience is that 80% do well when patient selected appropriately; should collect data.
  - Dr. R. Torrance Andrews, Society of Interventional Radiology (SIR), expressed his concerns about the process, believes that a vast literature supports efficacy were disregarded in report.
  - Dr. James Schamacher, arranged by Stryker Corporation, urged coverage; expressed that his patients have positives outcomes that are at odds with literature; concern that report included studies had bias in selection.
  - Dr. Oliver Ochs, Interventional Radiologist, urged coverage based on his clinical experience in seeing patient improvement; committee should wait until the registry data is available.
  - Dr. Robert Osnis, Interventional Radiologist, expressed his concerns that if this technology procedure was not covered the costs associated with medications and other cost factors would be more than the procedure; believes literature shows that this procedure is helpful to cancer patients.
  - Dr. J. Scott Bowen, Valley Medical Center, urged coverage based on clinical experience, time is critical factor (waiting for healing, fractures can cause severe debilitation, elderly need acceleration to ambulate) committee should await better evidence before denying; concerns with the placebo comparison studies.
- ✓ Open Public Comments: three individuals provided comments during the open portion
  - Dr. Ray Jensen, Interventional Radiologist, urged coverage for vertebroplasty and kyphoplasty, believes literature supports.

- Dr. Glen Davis, NASS, urged coverage for vertebroplasty based on Klassen study; success when apply stringent clinical selection; and coverage denial would be against professional guidelines including AAOS that support.
- Dr. Jeffrey Jarvik, Radiologist, pointed to Kallmes commentary who believes evidence, not anecdote should guide decision, and that for studies about pain, blinding is critical. In blinded, placebo control studies there were no differences, but both groups improved. There are no included studies on fracture due to cancer.

Agenda Item: Vertebroplasty, Kyphoplasty and Sacroplasty – Agency Comments

Dr. Jeff Thompson, Department of Social & Health Services, Medical Director, presented the agency utilization and outcomes for Vertebroplasty, Kyphoplasty and Sacroplasty to the committee, full presentation published with meeting materials.

- ✓ Background:
  - Fracture or compression result in considerable pain, loss of function and decreased quality of life.
  - Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body.
  - Kyphoplasty expands the partially collapsed vertebral body with an inflatable balloon before the injection of bone cement.
  - Sacroplasty involves the injection of bone cement into the sacrum to repair sacral insufficiency fractures.
- ✓ Agency Concerns:
  - Safety: Medium – therapies have risks of infection and cement embolism
  - Efficacy: Medium – short term, modest pain relief, no clear improvement in function; no evidence of longer term improvement in pain or function; RCTs shams studies show no differential benefit in pain.
  - Cost: Medium – usage and costs are escalating.
- ✓ Coverage Overview:
  - Currently covered by PEBB. Not covered by Medicaid or Labor and Industries (L&I).
- ✓ UMP Spends and Trends ~

Figure 1. UMP/PEP* Vertebral Augment (VA) Costs (+/- 3 day costs related by diagnosis)

Vertebral Augment Costs	2006	2007	2008	2009	Grand Total
Total Vertebral Augment Costs (3 day window of related charges)	$70,095	$156,750	$323,617	$318,081	$868,543*
Average Costs (UMP primary only)	$5,199	$11,516	$13,423	$10,837	$11,648
Minimum (UMP primary only)	$290	$722	$491	$1075	$290
Maximum	$11,815	$45,016	$42,130	$34,474	$45,016

*DSHS/DLI do not cover these procedures, and averaged 10 and 1 procedure(s)/year respectively.

- ✓ UMP Utilization by Procedure (some patients had both types of procedures within the same hospital or outpatient encounter) ~

Vertebral Augments	2006	2007	2008	2009	Overall
Vertebroplasty					
Procedures	25	31	53	55	164
Members	19	20	39	42	116
Total Costs	$16,590	$45,583	$99,705	$211,833	$373,711
Cost/Proc	$664	$1,470	$1,881	$3,852	$2,279*
Kyphoplasty					
Procedures	58	46	84	65	253
Members	45	26	53	45	170
Total Costs	$58,529	$121,275	$232,905	$273,983	$686,692
Cost/Proc	$1,009	$2,636	$2,773	$4,215	$2,714*
All Augments Summary					
Procedures	83	77	137	120	417
Members	64	46	92	87	286
Annual Cost	$70,095	$156,750	$323,617	$318,081	$868,543
Cost/Proc	$845	$2,036	$2,362	$2,651	$2,083

- Hayes rating at C or D
- Effect-size has diminished as quality of research has improved until no effect versus sham in 2 RCTs (editorial: Carragee EJ. The vertebroplasty affair: the mysterious case of the disappearing effect size. Spine J 2010; 10: 191-192).
- Placebo effect is real/statistically significant.
- "Control patients guessing vertebroplasty had significantly greater pain improvement at days 14 and 30 than did those guessing control (day 14, $P = .02$; day 30, $P < .001$). In the vertebroplasty group, no relationship between change in pain and patient guess was noted."

✓ Other considerations for Kyphoplasty:

- Kyphoplasty evolved from vertebroplasty
- More costly, less evidence
- Highest quality evidence shows kyphoplasty no better than vertebroplasty
- Best studies show vertebroplasty outcomes do not differ from sham
- No evidence on sacroplasty

✓ AMDG Recommendations:

- The evidence for effectiveness is lacking; there are safety concerns; there are sham RCTs showing no differences. The AMDG recommends a non-covered decision

Agenda Item: Evidence Review Presentation

Spectrum Research presented an overview of their evidence report on Vertebroplasty, Kyphoplasty and Sacroplasty, full presentation in meeting materials.

✓ *Scope of report:* Sacroplasty – very limited evidence from 9 case series of ≥ 5 patients (N = 141) is described in the report. In the absence of comparative studies no conclusions can be drawn regarding efficacy, effectiveness or safety. This presentation will focus on evidence related to vertebroplasty and kyphoplasty.

✓ *Background:* Vertebroplasty, kyphoplasty, and sacroplasty are surgical procedures used to treat spinal pain believed to be caused by fractures in the vertebra or sacrum. Cementoplasty techniques are intended to stabilize the fractured vertebra(e). Stabilization is thought to relieve pain, although

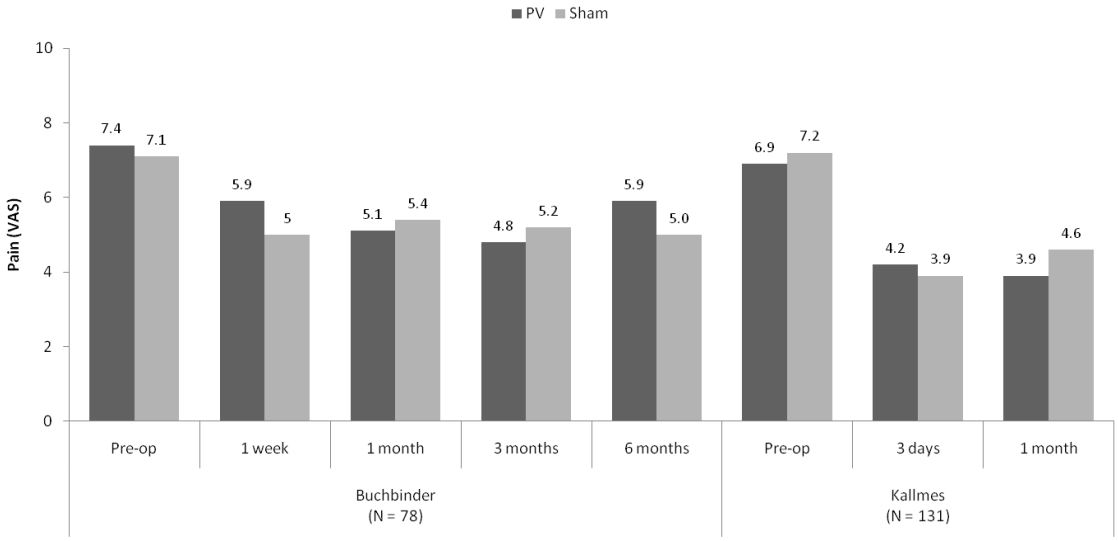
mechanism is not clear. Less invasive than alternative spinal surgical procedures, but more invasive than conservative medical therapy.

- ✓ Percutaneous vertebroplasty (PV) -- Injection of bone cement into partially collapsed vertebral body under computed tomography or fluoroscopic guidance.
- ✓ Balloon kyphoplasty (KP) -- Inflatable balloon is used to expand the collapsed body before injection of cement into the expanded cavity.
- ✓ *Outcomes:* Efficacy/effectiveness: primary measures -- Pain (various protocols for measurement) 0 - 10 scale (0 = no pain; 10 = worst pain ever). Functional outcomes -- Roland-Morris Disability Questionnaire (RDQ) and Oswestry Disability Index (ODI). Quality of life -- European Quality of Life - 5 Dimensions (EQ-5D) and Short Form General Health Survey (SF-36).
- ✓ Publications included for key questions 1 through 3: 11 RCTs and 23 observational trials. For key question 4: n = 3.
- ✓ Efficacy / Effectiveness on Vertebroplasty – 5 RCTs on osteoporotic fractures:
    - PV vs. sham surgery (2 LoE II studies): No statistically significant differences in pain or functioning in 2 RCTs (*n*s 78, 131). Trend toward greater proportion of PV patients achieving clinically significant improvement in pain.

- ✓ PV vs. CMT (3 LoE II studies): One large, adequately powered RCT (*n* = 188) reported PV significantly more effective than CMT for pain and functioning. In two small RCTs (*n*s 34, 50), PV and CMT patients comparable in pain relief, with inconsistent findings for functional outcomes.
- ✓ 4 cohort (LoE III) studies (*n*s 60-143): Pain relief and functioning improved more rapidly following PV. PV and CMT patients comparable after 6-12 months.
- ✓ Efficacy / Effectiveness on Kyphoplasty –
  - One LoE II RCT (*n* = 300): Significantly more initial improvement in pain and functioning after KP than CMT. KP and CMT similar outcomes by 12 months.
  - Two LoE III cohort studies (*n*s = 45, 60): KP reduced pain significantly more than CMT up to 3 years. KP improved a limited set of functional outcomes more than CMT.
- ✓ Efficacy / Effectiveness on Vertebroplasty vs. kyphoplasty –
  - One RCT (LoE II) (*n* = 100) and 10 cohort studies (LoE III) (*n*s = 20-54). PV and KP reduced pain by comparable amounts at follow-up periods up to 2 years. PV and KP showed comparable improvements on the Oswestry Disability Index.
- ✓ Efficacy of vertebroplasty (PV) vs. sham surgery – Clinically significant improvement in pain:

	Definition	PV	Sham	Follow-up
Buchbinder (2009)	≥ 2.5 points reduction	38%	38%	1 week
		51%	42%	1 month
		52%	35%	3 months
		54%	42%	6 months
Kallmes (2009)	30% reduction from baseline	64%	48%	1 month

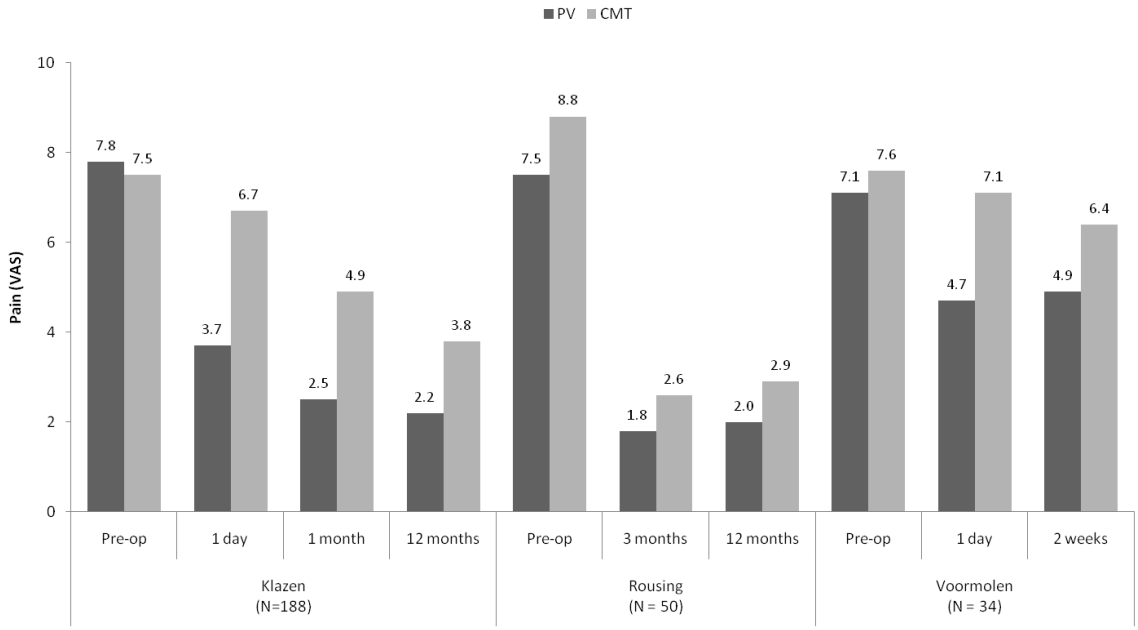
- ✓ Efficacy of vertebroplasty (PV) vs. sham surgery – Pain:



✓ Efficacy of PV vs. sham surgery – function and quality of life:

	PV	Sham	*p* value	Follow-up
Roland-Morris Disability Questionnaire (RDQ) (scale 0-23; higher scores *worse*)				
Buchbinder (2009)	13.6	12.0	ns	3 months
Kallmes (2009)	12.0	13.0	ns	1 month
European Quality of Life - 5 Dimensions (EQ5D) (scale 0-1; higher scores *better*)				
Buchbinder (2009)	0.50	0.48	ns	3 months
Kallmes (2009)	0.70	0.60	ns	1 month
Short Form General Health Survey (SF-36): Physical (scale 0-100; higher scores *better*)				
Kallmes (2009)	29.7	28.7	ns	1 month
Short Form General Health Survey (SF-36): Mental (scale 0-100; higher scores *better*)				
Kallmes (2009)	46.9	45.6	ns	1 month

✓ Efficacy of PV vs. conservative medical treatment (CMT) – Pain:



✓ Efficacy of PV vs. CMT – function and quality of life:

	PV	CMT	*p* value	Follow-up
Roland-Morris Disability Questionnaire (RDQ) (scale 0-23; higher scores *worse*)				
Klazen (2010)^	9.9	12.2	#	3 months
	<9	10.5	#	12 months
Voormolen (2007)	13	18	CI excludes 0	2 weeks
Short Form General Health Survey (SF-36): Physical (scale 0-100; higher scores *better*)				
Rousing (2010)	32.1	30.5	ns	12 months
Short Form General Health Survey (SF-36): Mental (scale 0-100; higher scores *better*)				
Rousing (2010)	48.7	49.0	ns	12 months
Quality of Life Questionnaire of European Foundation for Osteoporosis (QualEFFO) (scale 0-100; higher scores *worse*)				
Klazen (2010)^	40	44	#	3 months
	39	41	#	12 months
Voormolen (2007)	53	67	CI excludes 0	2 weeks

- ✓ Efficacy of kyphoplasty (KP) vs. CMT – Pain: Pain decreased significantly more in KP patients than in CMT patients over 12 months of follow-up. One week: 2.2 points differential improvement ($p < 0.001$). 12 months: 0.9 points differential improvement ($p < 0.01$). Early improvements in KP group followed by slower rate of improvement. (Wardlaw 2009; LoE II RCT, n = 300).
- ✓ Efficacy of PV vs. KP -- Pain decreased approximately 68% in PV and KP groups over 6 months of follow-up. No significant differences between PV and KP groups. SoE is very low (very poor quality study). (Liu 2010; LoE II RCT; n=100).

PV	KP	*p* value	Follow-up
Pain (0-10); higher scores *worse*			
7.9	8.0	ns	Pre-op
2.3	2.6	ns	3 days
2.6	2.6	ns	6 months

- ✓ Effectiveness of PV vs. CMT -- In 3 of the 4 studies, PV patients reported significantly less pain up to 6 months, but pain levels were comparable at 1 year. SoE is low.
- ✓ Effectiveness of KP vs. CMT -- In both cohort studies, KP patients improved significantly more than CMT patients. KP pain decrease: 25% and 62% in the two studies. CMT pain decrease: 0 and 43% in the two studies. SoE is very low.
- ✓ Effectiveness of PV vs. KP -- In 8 of the 10 studies that measured pain, no significant PV-KP differences were reported. In 4 of the 5 studies that measured ODI, no significant PV-KP differences were reported. SoE is low.
- ✓ Safety (strength of evidence = very low):
    - *New fractures:* Rates varied across studies; no consistent pattern for PV, KP, or CMT and new fractures occur in the absence of cement augmentation.
    - *Cement leakage:* Asymptomatic leakage common; more likely in PV (19.7% - 79.0%) vs. KP (0.51% -11.2) – pooled estimates and pooled rates-symptomatic leakage low (PV, 0.5% -1.6% ; 0% -0.3%, KP).
    - *Cement embolism:* 26%, asymptomatic, systematically assessed in 1 RCT and pooled estimates: 1.6% asymptomatic (62/3774); 1.1% symptomatic (16/1431) in SR of case series; where symptoms unknown 0.4%-1.6%.
    - *Mortality:* Perioperative: KP, 0.01% (11 case series); PV, 2.1% (57 case series). Overall mortality difficult to interpret: patient characteristics and timing.

✓ *Safety Outcomes of PV and KP:*

	PV	KP	CMT or sham surgery	Risk difference (range)	Follow-up (range)
Percent of patients with any new fracture (range)					
7 RCTs	0 - 30.4	4.0 - 33	0 - 25.3	-2.5 - 12.3	3 - 12 mo
11 cohort studies	0 - 31.3	0 - 41.2	4.7 - 71.4	-30.2 - 19.6	3 mo - 3 yrs
Systematic reviews	18 - 19.7	7 - 17			
Proportion of new fractures that were adjacent to treated vertebra					
1 RCT	38%		37%		12 mo
Systematic reviews	52%	75%			

	PV	KP	Risk difference (range)	Follow-up (range)
Percent of patients with asymptomatic cement leakage (range)				
3 RCTs	37 - 80	27		12 mo
11 cohort studies	0 - 87.5	0 - 49.3	-1.4 - 50	1 - 3 yrs
Systematic reviews	20 - 79	13 - 14		
Percent of patients with symptomatic cement leakage (range)				
Systematic reviews	0.5 - 1.6	0 - 0.3		
Percent of patients with pulmonary cement embolism				
1 RCT	26 (asymptomatic)		12 mo	
Systematic reviews	0.9 – 1.6*	0.1 – 0.4	variable	

	PV	KP
Percent with procedural complications (range) (fracture, neurological, dural tear, infection, subcutaneous hematoma, balloon rupture)		
Systematic reviews	2.4 – 3.8	0.4 – 0.6
Percent with medical complications (range) (respiratory, cardiovascular, stroke, pneumonia, fever)		
Systematic reviews	0.4 – 2.8	0.9 – 3.2
Percent mortality (perioperative)		
Systematic reviews	2.1% (14/680)	0.01% (1/406)
Percent mortality (unspecified time period)		
Systematic reviews	0.6 - 2.1	2.3 - 3.2%

✓ Differential effectiveness, efficacy and safety (strength of evidence = very low):

- No comparative studies assessing differential outcomes of PV and KP by gender, age, comorbidities. No comparative studies assessing differential outcomes by fracture etiology (osteoporotic or tumor-related).
    - Majority of comparative studies included only patients with osteoporotic fractures.
- No studies were designed to compare outcomes for patients with different fracture ages
- Post-hoc analyses in 2 RCTs indicated that pain outcomes did not differ significantly for patients with acute vs. chronic fractures; Low power for this analysis. Largest RCT of PV vs. CMT included only acute fractures; conclusions about efficacy for different fracture ages cannot be drawn. 4 cohort studies: Conflicting results on fracture age – 2 studies of pain duration ≤ 6wks pain, PV significantly ↓ pain vs. CMT; 2 with longer duration (≤ 3 or 12 months) also reported pain improvement with PV.

✓ Cost effectiveness (strength of evidence = very low): Three studies incorporated economic evaluations. 2 studies looked at PV versus CMT, 1 at KP versus CMT. All were of populations with osteoporotic fractures. None were from the United States, therefore applicability unclear. Data only available up to 12 months. Efficacy/effectiveness in high quality studies is uncertain making cost-effectiveness unclear.

- Incremental cost effectiveness ratios (ICER) at one year ranged from €22,685 per QALY (PV, Klazen, funding-Cook Medical) to £8840 per QALY (KP, Ström, funded by Medtronic) vs. conservative treatment. Masala study: Cost/patient for one-point improvement (11-point pain scale) at one year slightly lower for PV (€ 529) than CMT (€ 632).

✓ Issues to Consider:

- Most data are from osteoporotic fractures; less is known about fractures due to malignancy. Longer term outcomes are unknown.
    - Most comparative studies have relatively short follow-up periods
    - Age of patient population complicates the examination of longer-term outcomes
- Clinically meaningful improvement (Pain, RMDQ)
    - Statistically significant differences may not represent clinically meaningful change
    - Definition of meaningful improvement not settled
- Outcomes measures, definitions varied across studies making summary and comparison across studies challenging
- Detection of adverse events
    - Fractures and cement emboli may go undetected outside of a clinical trial with systematic assessment
    - Differing perspectives on significance of asymptomatic events
    - Sensitivity of diagnostic tools for embolism (CT vs. radiographs, fluoroscopy)

Agenda Item: HTCC Vertebroplasty, Kyphoplasty and Sacroplasty Discussion and Findings

Dr. Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of Vertebroplasty, Kyphoplasty and Sacroplasty beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

1. Evidence availability and technology features

1.1 The evidence based technology assessment report indicates that vertebral compression fractures and sacral insufficiency fractures occur, commonly as part of the natural disease progression of osteoporosis or osteopenia. Some patients with fractures are asymptomatic but others experience acute pain, loss of function, and decreased quality of life thought to be caused by the fracture.

1.2 Vertebroplasty (PV), kyphoplasty (KP) and sacroplasty are all cementoplasty techniques that aim to relieve pain thought to be caused by the fracture by stabilizing the fractured bone(s). Vertebroplasty and sacroplasty are considered minimally invasive procedures and are usually performed using only local anesthesia or with conscious sedation. General anesthesia may be

used. Kyphoplasty almost always requires general anesthesia and at least one overnight stay in the hospital. The patient must lie prone during all three procedures. Multiple levels can be treated during the same session. Patients are usually selected based on failure of conservative treatment or incapacitating pain. Alternatives include conservative management and surgical fixation, though invasive surgery may be problematic due to common comorbidities in the elderly and female population most often considered for this treatment.

1.3 Despite increasing use of these procedures (rates of kyphoplasty doubled between 2001 and 205), the evidence for the procedure remains low and the efficacy, safety and economic impact are not well understood. Patients are generally elderly women with osteopenic fractures and most included studies focused on this population.

1.4 The timing of intervention is an important consideration. Most patients are successfully treated with conservative care which resolves pain in 4 to 6 weeks and is generally recommended first. However, patients with acute fractures (less than six weeks) may be more likely to experience pain relief and the rapid recovery from debilitating pain is a primary treatment aim. Fracture age is difficult to determine as patients may have difficulty pinpointing the onset of pain and whether a certain event may be associated with the onset.

1.5 In addition to typical complications from invasive procedures, cementoplasty techniques include risk of possible increase of subsequent compression fractures near a cemented vertebra due to increased rigidity of the treated vertebrae and risk of cement leakage.

1.6 Evidence included in the technology assessment review was obtained through systematic searches of the medical literature for systematic reviews including meta-analyses, randomized controlled trials, observational studies, and economic studies. 11 RCTs, 23 Observational studies, and 3 economic studies met inclusion criteria and were included in the review. Overall strength of evidence from these studies was low to very low or inconclusive. Two RCTs compared vertebroplasty with sham procedure; three RCTs compared vertebroplasty to conservative care; one RCT compared kyphoplasty to conservative care; and one RCT compared kyphoplasty and vertebroplasty.

- The evidence based technology assessment report identified 4 clinical guidelines; there is no National Coverage decision on vertebroplasty, kyphoplasty or sacroplasty.
- The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, clinical expert, HTA program, agency medical directors and the public.

2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

2.1 The evidence based technology assessment report concluded that the overall strength of evidence for safety is low for vertebroplasty and kyphoplasty and very low for sacroplasty and evidence based estimate of effect are uncertain. While it appears that rates of serious complications are low for vertebroplasty and kyphoplasty, studies with long-term (> 5 year) follow-up are few and comparative studies, especially RCTs, may have too few patients to detect more rare but serious outcomes. Primary safety outcomes reported include rates of new fracture, cement leakage, pulmonary cement embolism, and mortality related to vertebroplasty and kyphoplasty.

2.2 *New fractures (adjacent or non-adjacent)* – in comparative studies, rates of new fractures were up to 30% at 12 months, with no consistent pattern across studies of increased fracture rates for any one treatment (vertebroplasty, kyphoplasty, or conservative treatment). One RCT reported that the distribution of fracture location (adjacent or non-adjacent) was similar for vertebroplasty and non-surgical patients. Systematic reviews, incorporating information on longer-term follow-up with a large (pooled) number of patients in case series, suggest that

rates of new fracture may be slightly higher in vertebroplasty (18-19% of patients, 16-21% of vertebral levels) than kyphoplasty (7-17% of patients, 11-13% of levels). One systematic review concluded that the proportion of new fractures that were in adjacent vertebrae was higher for kyphoplasty (75%) than for vertebroplasty (52%).

2.3 C*ement leakage* – in comparative studies, rates of cement leakage (largely asymptomatic) approached 80% for vertebroplasty and 50% for kyphoplasty, with some evidence that leakage is more common with vertebroplasty than with kyphoplasty. Systematic reviews also suggest that leakage is more common in vertebroplasty (19.7% - 79.0% of levels treated) than in kyphoplasty (0.51% - 11.2%), and that rates of symptomatic leakage are quite low (0.5%-1.6%of levels treated for vertebroplasty and 0% - 0.3% for kyphoplasty).

2.4 *Pulmonary cement embolism* – As a result of differential surveillance in RCTs, non-randomized studies, and case series, rates vary widely across studies. One RCT using computed tomography to detect emboli reported that 26% (15/54) of vertebroplasty patients had a cement embolism, all of which were asymptomatic. No incidents of symptomatic embolism were reported in comparative studies. A systematic review of cement embolism reported rates of 1.6% for asymptomatic PCE and 1.1% for symptomatic PCE (all but one of the case series included in the review were of vertebroplasty patients).

2.5 *Mortality* – systematic reviews (based on case series) estimate mortality rates at 2.1% for vertebroplasty and 2.3%-3.2% for kyphoplasty; the timing of mortality was not reported. Peri-operative mortality rate for kyphoplasty was .01% across 11 case series. Since the majority of patients receiving these procedures are elderly and/or have malignant disease, the extent to which mortality can be attributed to the procedures is unclear.

2.6 Sacroplasty – the evidence based technology assessment report indicates that the overall strength of evidence about safety of sacroplasty is very low, and all data are from case series. Cement leakage was the only reported complication and occurred in 7 of 34 (20.6%) patients across four case series.

3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

3.1 Vertebroplasty:

- *Pain Relief* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of vertebroplasty to reduce/relieve pain is *low*; any effect estimate is uncertain and may change with additional research. The low strength of evidence and lack of ability to estimate effect based on evidence is due to the limitations of the studies and that the studies reported differing outcomes (some studies showed benefit others did not). The RCTs were limited to patients with osteoporotic fractures and evaluated short-term effects (≤12 months). Two sham-controlled RCTs demonstrated no difference in pain relief (up to 1month in one study and 6 months in the other), though both studies were limited in power to detect differences in the proportion of patients with clinically meaningful improvement. Another RCT demonstrated statistically significant improvement in pain scores sustained to the 12-month follow-up compared to conservative care and included more patients but was not blinded and did not include a placebo comparison. Two small RCTs reported no advantage for vertebroplasty over 2 weeks or 12 months. Four nonrandomized studies with follow-up up to one year found that vertebroplasty was more effective in reducing pain than conservative medical treatment at up to approximately six months, but no difference at one year.

- *Function and quality of life* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of vertebroplasty to improve patient function or quality of life is *low*; any effect estimate is uncertain and may change with additional research. One larger RCT demonstrated that PV was more effective than conservative treatment in improving functioning as measured by the QualEffo and RDQ, although it is possible that early differences in improvement diminish over time. Two small RCTs found comparable improvements in function over 2 weeks and 12 months for vertebroplasty and non-surgical patients. In 4 non-randomized studies, vertebroplasty showed superior effectiveness in improvements in functioning and quality of life in the first 3-6 months was followed by equivalence at one year.

3.2 Kyphoplasty:

- *Pain Relief* – the evidence based technology assessment report concluded that the overall strength of evidence about effectiveness of kyphoplasty to relieve/reduce pain is very *low*; any effect estimate is uncertain and may change with additional research.
- Only one RCT compared kyphoplasty with conservative treatment, reporting that while pain was reduced more rapidly in kyphoplasty patients, this advantage over conservative treatment was diminished by the one-year follow-up. Because of the paucity of RCTs comparing kyphoplasty to conservative treatment, the overall strength of evidence is low and effect estimates may change with additional research. In two non-randomized studies, kyphoplasty reduced pain more than conservative medical treatment for periods up to 3 years.
- *Function and quality of life* – the evidence based technology assessment report indicated that it is uncertain whether kyphoplasty improves patient functioning and quality of life. In these two studies, kyphoplasty improved a limited set of functional outcomes more than conservative medical treatment.

3.3 Sacroplasty: There is no evidence of efficacy for sacroplasty. Very limited data from 9 case series (N = 141 total patients) is available, the case series showed pain relief with sacroplasty; but the absence of comparative studies, small patient size do not permit an evidence based conclusion.

4. Special Populations

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has differential effects. Summary of committee considerations follows.

4.1 The evidence based technology report concluded that there is insufficient evidence for any conclusion of differential effect.

4.2 Fracture age was one key potential differentiator; however no studies were designed to directly compare efficacy or safety outcomes between patients with acute, sub-acute, and/or chronic fractures. Two RCTs reported that improvements in pain and functional outcomes were not significantly different for patients with acute and chronic fractures; however, the studies may not have had adequate power for these post-hoc analyses. One RCT of PV vs. CMT in patients with acute fractures reported greater improvement in pain and function for PV patients, but evidence for differential efficacy cannot be derived since there was no direct comparison with more chronic fractures in the same underlying population

4.3 The evidence based technology assessment report indicates that no studies were found that addressed differential efficacy or safety issues for subpopulations defined by gender, age, psychological or psychosocial co-morbidities, provider characteristics, or payer type.

4.4 Diagnosis (osteoporosis or tumor-related fractures) – the evidence based technology assessment report indicates that there are no studies that assessed differential outcomes of vertebroplasty or kyphoplasty by fracture etiology. The majority of studies were limited to

patients with osteoporotic fractures. Only two retrospective cohort studies (both comparing vertebroplasty with kyphoplasty) studied patients with fractures due to malignancy, with one study reporting comparable outcomes both procedures and the other reporting that kyphoplasty led to more improvement in pain than vertebroplasty over one year.

5. Evidence about the technology's value and cost-effectiveness

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

5.1 The evidence based technology report summarized three economic studies, however, because the evidence about efficacy, effectiveness, and safety is low to very low and evidence based estimates of effect are uncertain; conclusions about cost effectiveness are premature. No cost studies were conducted with U.S. data, the cost effectiveness of vertebroplasty, kyphoplasty or sacroplasty in a US setting is unknown.

5.2 The economic impact of complications, reoperation, or revision following vertebroplasty, kyphoplasty, or sacroplasty is unknown.

5.3 Washington state agency utilization and cost information indicates that the single agency that reimburses (UMP) for these procedures expended $868,543 in the last four years, with an average cost of $10,837; and both procedure volume and costs are rising annually.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report. Overall, the clinical guidelines and Medicare coverage decisions included in the evidence report and the AAOS guideline published subsequent either do not cite evidence or rely on evidence assess as low or very low quality or consensus statements.

6.1 Centers for Medicare and Medicaid Services (CMS) have no published National or Local coverage determinations for vertebroplasty, kyphoplasty or sacroplasty.

6.2 The evidence based technology assessment report identified three guidelines on vertebroplasty, kyphoplasty and/or sacroplasty, although no guideline specifically addressed the procedures for osteoporosis or malignancy – the studied indications.

- Two guidelines mentioned vertebroplasty and kyphoplasty as part of the assessment and management of spinal cord compression and chronic pain and indicate they may be considered.
  - Institute for Clinical Systems Improvement (ICSI), 2008
  - National Collaborating Centre for Cancer, National Institute for Health and Clinical Excellence (NICE), 2008
- *American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons / Congress of Neurological Surgeons, and American Society of Spine Radiology* -- A consensus statement on percutaneous vertebral augmentation was developed: "It is the position of the Societies that vertebral augmentation with vertebroplasty or kyphoplasty is a medically appropriate therapy for the treatment of painful vertebral compression fractures refractory to medical therapy when performed for the medical indications outlined in the published standards[1-3]."
- *American Association of Orthopaedic Surgeons (AAOS)* -- recommend against vertebroplasty for patients who present with an osteoporotic spinal compression fracture on imaging with correlating clinical signs and symptoms and who are neurologically intact. *Strength of Recommendation: Strong.* Kyphoplasty is an option for patients who present with an osteoporotic spinal compression fracture on imaging with correlating

clinical signs and symptoms and who are neurologically intact. *Strength of Recommendation: Weak*.

Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

1. Evidence availability and technology features

The committee concludes that the best available evidence on Vertebroplasty, Kyphoplasty and Sacroplasty has been collected and summarized through the evidence based technology assessment report; public and agency comment.

1.1. The committee agreed that severe spinal pain, often in elderly and cancer patients that is thought to be related to vertebral compression fractures causes significant morbidity and impact on function and quality of life. While fractures often heal without intervention within a month, some do not and the rapid resolution from debilitating pain can be important to reduce co-morbid risks. The committee agreed that rapid pain resolution or large pain relief measured in very short time (one day to one week) is an important outcome if accompanied by change in function (e.g. bed bound to ability to care for self). Additional important patient outcomes are pain relief measured over time, impact on function and quality of life.

1.2. The committee agreed that not all vertebral compression fractures are accompanied by pain; dating the vertebral fracture is important but difficult due to poor symptom correlation; the mechanism of pain and pain relief is not well understood; and the impact of natural disease progression and the appropriate timing of the intervention remain unclear. Acute fractures are suggested to be more amenable to treatment than older fractures; but acute fractures are more likely to resolve without intervention and common treatment guidelines suggest conservative care first.

1.3. Vertebroplasty involves injection of bone cement into the vertebral body to treat the spinal pain thought to be caused by the fractures. Kyphoplasty and sacroplasty are extensions or modifications of Vertebroplasty.

1.4. The committee agreed that the overall strength of evidence from was low to very low or inconclusive. The evidence was limited to generally poor and very poor studies with short follow up times; limited populations; weak comparators; and variable measures. The evidence conflicted, with two randomized, double blind trials resulting in similar findings of no difference compared to sham procedures; whereas five non blinded trials (without sham) and the observational studies generally resulted in effect favoring vertebroplasty or kyphoplasty on pain and function, at least in short term.

1.5. The committee agreed that the differences between the very rapid and significant changes reported by clinicians and the effect reported in the literature are disparate; even studies showing positive effect are mostly moderate. The committee agreed that especially in pain measurement, the importance of blinding and measuring placebo effect is critical to an accurate understanding of whether the intervention is causally related to changes.

1.6. The committee agreed that the evidence report accurately concludes that evidence about sacroplasty, consisting of small case series is too limited to draw any evidence based estimates of effect related to safety, efficacy, effectiveness or cost and that the technology is currently unproven. Further discussion focused of evidence focused on vertebroplasty and kyphoplasty.

2. Is it safe?

A majority of the committee concludes that the comprehensive evidence about safety of sacroplasty, vertebroplasty and kyphoplasty is insufficient, and thus safety of these procedures is unproven.

2.1. The committee agreed that there is insufficient evidence about the safety of sacroplasty.
2.2. The committee agreed that complications were not infrequent (approximately 25%); the procedures are invasive and have some risk. There isn't evidence that mortality is affected.
2.3. Overall there is insufficient evidence due to small sample size, lack of information about clinical significance, and effect over time which precludes an evidence based conclusion.
2.4. The committee agreed that cement leakage and increased fracture rates were the primary noted complications.
- Rates of new fractures were up to 30% at 12 months, with no consistent pattern across studies of increased fracture rates for any one treatment (vertebroplasty, kyphoplasty, or conservative treatment) though one review suggested new fractures may be higher in vertebroplasty and another suggested kyphoplasty had higher rates.
- The committee agreed that the rate of cement leakage varied but is significant approaching 80% for vertebroplasty and 50% for kyphoplasty. The evidence is unclear about clinical effect as most cement leakage is asymptomatic, but no longer term data.

3. Is it effective?

A majority of the committee agreed that the effectiveness of Kyphoplasty and Sacroplasty was unproven. The committee split on whether the evidence of effectiveness of Vertebroplasty was insufficient (5) or equivalent (5).

3.1. The committee agreed that there is insufficient evidence about the efficacy and effectiveness of Sacroplasty.
3.2. The committee agreed that there was the most evidence about efficacy and effectiveness of vertebroplasty (the original intervention), although the overall strength of evidence is low because of trial limitations and conflicting results. Two sham controlled RCTs found no differences for effect on pain or function, while a larger RCT found statistically significant benefit in pain relief and function compared to conservative care. The magnitude of pain relief is also unclear –sham controlled studies report a 2 to 3 point decrease; meeting a minimal to moderate decrease; while other RCTs found a 1 to 6 point reduction.
- For some committee members, the evidence of effectiveness is insufficient because the studies were overall low quality and all had limitations, but the higher quality design of two double-blind, sham controlled studies showing no difference is predominate. While not yet conclusive of no effect, it requires further well designed and sham control studies to overcome.
- For some committee members, the evidence was weak but demonstrated equivalence to current conservative management because all interventions showed some improvement (although the mechanism is unclear); the 2 sham controlled studies lacked power to detect differences in the proportion of patients with clinically meaningful improvement; and the larger RCT, along with observational studies, shows improvement. Further well designed studies (including sham) and with larger patient sizes are desirable.

3.3. The committee agreed that there is insufficient evidence about the efficacy and effectiveness of kyphoplasty. The strength of evidence is very low and likely to change with further research. The procedure is predicated on vertebroplasty which has conflicting evidence; a single RCT and several cohort studies showed more rapid improvement but differences diminished over time; the pain outcomes were not absolute but measured as differences between groups and found differences ranging from 2.2 to 0.9, which limits interpretation on overall improvement and clinically meaningful difference.
3.4. The committee agreed that no difference was demonstrated between vertebroplasty and kyphoplasty; though this was not determinative as more evidence of the efficacy of each procedure is needed.

4. Evidence about the technology's special populations, patient characteristics and adjunct treatment

The committee agreed that no compelling evidence exists to differentiate sub groups or special populations.

4.1. The committee agreed with the evidence based report that no evidence is available to conclude whether the procedures have differential safety or efficacy.

5. Is it cost-effective?

The committee concludes that Vertebroplasty, Kyphoplasty and Sacroplasty is unproven to be cost effective; agreeing with the comprehensive evidence review that no evidence based conclusions about cost effectiveness can be drawn.

5.1. The committee agreed that due to the lack of evidence on effectiveness, cost effectiveness is inconclusive.

5.2. The committee agreed that Washington state agency utilization and cost information shows substantial costs that are increasing.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, and agency and state utilization information. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee concluded that the current evidence demonstrates that there is insufficient evidence, and that the safety, efficacy and cost of vertebroplasty, kyphoplasty and Sacroplasty are unproven. Based on these findings, the committee voted 10 to 0 to not cover Vertebroplasty, Kyphoplasty or Sacroplasty.

Vertebroplasty, Kyphoplasty and Sacroplasty Evidence and Coverage Vote

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Vertebroplasty --
Is there sufficient evidence under some or all situations that Vertebroplasty is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**5**	**5**	0	**0**
Safe	**7**	**2**	**1**	0
Cost-effective Overall	**8**	0	**2**	0

Kyphoplasty --
Is there sufficient evidence under some or all situations that Kyphoplasty is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**8**	**2**	0	0
Safe	**6**	**2**	**2**	0
Cost-effective Overall	**8**	0	**2**	0

Sacroplasty --
Is there sufficient evidence under some or all situations that Sacroplasty is:

	Unproven (no)	**Equivalent** (yes)	**Less** (yes)	**More** (yes)
Effective	**10**	0	0	0
Safe	**9**	0	**1**	0
Cost-effective Overall	**10**	0	0	0

The committee discussed Clinical guidelines and Medicare decision. The committee decision is not in conflict with Medicare; and is consistent with one guideline; is not in conflict with (neutral) with respect to guidelines listing interventions as options; and inconsistent with one guideline recommending the procedures.

There is no National Medicare Coverage decision. Four identified guidelines: the guidelines did not specifically address the three procedures as treatment for vertebral compression fractures due to osteoporosis or malignancy – the indications for which there is research; though four guidelines mention the procedures. Two guidelines from 2008 include kyphoplasty and vertebroplasty as options – one for chronic pain and one for malignancy. One consensus statement of three medical societies indicates vertebroplasty or kyphoplasty are medically appropriate; and one guideline strongly recommends against vertebroplasty and weakly supports kyphoplasty as an option. The guidelines did not focus on specifically on the conditions for which there is clinical evidence and several predate the seminal studies (2009-2010) reviewed here. Guidelines did not address the strength of the placebo effect and differences of findings in the sham control RCTs and did not address the cost or cost effectiveness. The committee found that the evidence based technology assessment summarized the most recent, relevant evidence and assessed its quality along with addressing key questions relevant to the committee's statutory criteria including evidence on safety, efficacy, effectiveness and cost that were not addressed or transparent in clinical guidelines.

Vertebroplasty, Kyphoplasty and Sacroplasty Coverage Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

HTCC COMMITTEE COVERAGE DETERMINATION			
	Not covered	**Covered Unconditionally**	**Covered Under Certain Conditions**
Vertebroplasty	**10**	0	0
Kyphoplasty	**10**	0	0
Sacroplasty	**10**	0	0

- Action: The committee chair directed HTA staff to prepare a Findings and Decision document on Vertebroplasty, Kyphoplasty and Sacroplasty reflective of the majority vote for final approval at the next public meeting.

Agenda Item: ABA Therapy for Autism Staff Update

Leah Hole-Curry, HTA Program Director, provided an ABA Therapy for Autism staff update:

- ✓ HTA selected ABA Therapy for Autism Spectrum Disorder (ASD) to undergo a health technology assessment where an independent vendor systematically reviews the evidence available on its safety, efficacy, and cost-effectiveness, and then an independent committee of health care providers (HTCC) makes a coverage decision for state agencies. HTA posted the topic and gathered public input on all available evidence. HTA posts Key questions which guide the development of the draft evidence report. In this case, HTA posted the key questions from a federal agency, Agency for Healthcare Research and Quality, AHRQ, who is already conducting an evidence review on interventions for ASD, including ABA Therapy. When using an evidence report developed by another entity, HTA ensures that standards and questions relevant to the HTCC are met, supplemented by additional materials. HTA is providing a staff update on the topic and seeking input from the HTCC at its public meeting to guide development of the report(s).
- ✓ Report Status: AHRQ selected the topic of Therapies for Children with Autism Spectrum Disorders in 2009. The research protocol and key questions were finalized in December 2009. The proposed report scope is broader than the WA HTA topic, but the key questions include ABA therapy as one of multiple interventions for review and comparison. A draft evidence report was posted for comment in August 2010 and is now undergoing revision based on public comments and peer review.
    - Staff will have to await the final evidence report before determining whether the methods are substantially similar to HTA commissioned work, which is necessary given our program purpose. For ABA Therapy there has been substantial debate on trial inclusion criteria and appropriate evidence standards because, as detailed further below, this service has been called educational, behavioral, and medical; and each may use different evaluation approaches. Finally outcomes of interest can vary among the disciplines, and HTA needs to ensure that all patient oriented clinical outcomes are addressed.
- ✓ Supplemental Materials: The AHRQ report will not have any information on guidelines, Medicare and other coverage policies, WA state agency utilization and experience data, or WA prevalence information.
    - The MED OHSU project, has completed a quality review of two primary Autism treatment guidelines (National Autism Council (NAC) and Scottish Intercollegiate Guidelines Network (SIGN)); a review of state policies; and information about single subject study design
    - OHSU can incorporate WA utilization, cost, and experience data as necessary and provide an overview linking the evidence review and supplemental materials, or will perform the evidence review if the AHRQ report does not meet program needs.
- ✓ A wide range of psycho-educational, speech therapy, occupational therapy and physical therapy interventions are available, incorporating a mix of behavioral, developmental and education approaches. These services may be provided by professionals in a variety of settings and by or with the involvement of families. Interventions can include services that (a) are called

"treatments" and billed as health care services if performed by an appropriately licensed professional; (b) can be delivered by educators, speech language pathologists, or psychologists interchangeably (or by unlicensed individuals under their supervision) in either health care or educational settings; or (c) may be provided by people who are not licensed. The recent AHRQ draft report identifies the following categories: behavioral interventions; educational interventions; medical and related interventions; allied health interventions and complementary and alternative medicine interventions (CAM).

- ✓ Controversy: There is debate over whether the interventions found most successful for young children on the Spectrum are best described as educational or medical; medical systems are not well designed for coordinating and integrating care with other service providers and there is disagreement whether the interventions meet the appropriate standard of evidence for medical insurance.

Agenda Item: Spinal Fusion Update

Brian Budenholzer, HTCC Chair, and Leah Hole-Curry, HTA Program Director, provided an update on Spinal Fusion:

- ✓ HTCC made a decision in November 2007 to cover lumbar fusion, with conditions. The condition was a "failure or inability to access a structured, intensive, multi-disciplinary program". The Department of Labor & Industries has implemented the coverage policy and a structured, intensive, multi-disciplinary program requirement. In late summer 2010, L&I made a request to the HTA program for guidance based on a discussion and disagreement with a stakeholder about implementation.
    - The HTA program agreed to raise the stakeholder disagreement with the Chair for potential committee action. The L&I policy is to approve fusions at one-level only (this is based on their historical policy for fusion and is maintained here). The stakeholder contends this is inappropriate because the HTCC coverage decision does not include a restriction on number of levels.
    - Staff actions – reviewed decision and topic materials and discussed with Chair. HTCC decision and key questions and minutes were reviewed. The key questions did not include this issue; and the HTCC coverage decision is silent on this issue. The minutes do not reflect discussion of this issue. The Evidence Report does not separately address the issue in response to key questions.
- ✓ Outcome: The chair made the decision that further action of the committee isn't needed, but wanted to update you on this topic and hear discussion. If there is substantial disagreement, then we'll decide on the appropriate information needed for further action and have staff prepare that for a later committee meeting. After the Chair was briefed on the concern and the reviewed the materials, it was clear that this particular issue – the number of levels – was not raised to the HTCC via the topic and key questions, and was not addressed in the HTCC decision, nor did the evidence report call out an analysis on it.
    - Agencies retain full authority to implement policy that is not included in the HTCC decision. For HTCC decisions, agencies are to implement according to their processes and have latitude to do so as long as it isn't inconsistent with the HTCC.
    - Since the topic and HTCC decision is silent on this, the implementation is not inconsistent and is within the agency's purview.
    - If the stakeholder would like this topic addressed specifically, any stakeholder can request a review through the HTA's Interested Party Petition, and if selected a review of this issue could be conducted and the HTCC would then make a coverage decision.

Agenda Item: Leadership Acknowledgement and Change

Leah Hole-Curry, HTA Program Director, addressed the leadership acknowledgement and change to the Health Technology Clinical Committee (HTCC).

- ✓ Dr. Brian Budenholzer, HTCC Chair, is resigning his chairmanship due to a new job opportunity on the east coast. The HTCC vice-chair, Craige Blackmore, has accepted the HTCC Chair position.
- ✓ The program is in the process of appointing a new vice-chair