

Health Technology Clinical Committee

Date: September 16th, 2011

Time: 8:00 am – 3:30 pm

Location: SeaTac Airport Conference Center – Central Auditorium

Adopted:

HTCC MINUTES

Members Present: Dr. Carson Odegard; Dr. Richard Phillips; Dr. Craig Blackmore; Dr. Marie-Annette Brown; Dr. Kevin Walsh; Dr. Christopher Standaert; Dr. Michelle Simon; Dr. Joann Elmore; Dr. Michael Souter; Dr. Seth Schwartz and Dr. David McCulloch.

HTCC FORMAL ACTION

1. **Call to Order:** Dr. Blackmore, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **June 17th, 2011 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, and adopted by the committee.
 - *Action: Eight committee members approved the June 17th, 2011 meeting minutes. Three committee members abstained from voting.*
3. **Applied Behavioral Analysis (ABA or ABA Therapy) based Behavioral Interventions for the Treatment of Autism Spectrum Disorder draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The ABA findings & decision was approved and adopted by the committee.
 - *Action: Ten committee members approved the ABA Therapy findings & decision document. One committee members abstained from voting.*
4. **Positron Emission Tomography (PET) Scans for Lymphoma:** The HTCC reviewed and considered the PET technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. 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 |
| Positron Emission Tomography (PET) Scans for Lymphoma | 0 | 1 | 10 |

- ✓ **Discussion:** The Chair called for discussion on conditions related to PET due to the majority voting for coverage. The following conditions were discussed and approved by a majority:
 - **Limitations of Coverage:** Positron Emission Tomography (PET) scans for Lymphoma is a covered benefit when the following conditions are met:
 1. One scan for initial treatment planning;

Draft Version Not Officially Adopted



- 2. Additional scans for restaging with clinical suspicion of disease progression or treatment failure subject to agency approval;
- 3. No coverage for routine surveillance

✓ *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on PET reflective of the majority vote.

5. Hip Surgery for Femoroacetabular Impingement Syndrome (FAI): The HTCC reviewed and considered the FAI technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA program, an invited clinical expert, the public and agency medical directors. 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 |
| Hip Surgery for Femoroacetabular Impingement Syndrome (FAI) | 9 | 0 | 2 |

✓ *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on FAI 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 September 16th, 2011

Agenda Item: Meeting Open and HTA Program Update

Dr. Craig Blackmore, HTCC Chair, opened the public meeting.

- ✓ New committee member, Dr. David McCulloch, was introduced
- ✓ Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics and introductions.
 - Newly hired HTA Program Director, Josh Morse, was introduced. Josh Morse will start officially at HCA-HTA on October 1st, 2011.

Agenda Item: Previous Meeting Business

June 17th, 2011 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: Eight committee members approved the June 17th, 2011 meeting minutes. Three committee members abstained from voting.*

Applied Behavioral Analysis (ABA or ABA Therapy) based Behavioral Interventions for the Treatment of Autism Spectrum Disorder draft Findings & 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. Five public comments were received, included in the meeting materials, and were reviewed and discussed.

- *Action: Ten committee members approved the ABA Therapy findings & decision document. One committee members abstained from voting.*

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:
 - 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: Positron Emission Tomography (PET) Scans for Lymphoma 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 PET review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert; Dr. Janet Eary is a Professor of Radiology, working in Nuclear Medicine and Molecular Imaging. Dr. Eary completed a conflict of interest and indicated no conflicts.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: No stakeholders scheduled time for public comments.
- ✓ Open Public Comments: No individuals provided comments during the open portion.

Agenda Item: PET Topic – Agency Comments

Dr. Jeff Thompson, Medical Director, Health Care Authority, presented the agency utilization and outcomes for PET to the committee, full presentation published with meeting materials.

- ✓ PET Background:
 - Positron emission tomography (PET) is a diagnostic imaging test using a positron emitting radioactive particle.
 - In using PET for cancer, the radioactive particle is usually 18fluorine (18F) which is incorporated into a glucose molecule. 18FDG preferentially accumulates in areas of high glucose metabolism such as areas of active cancer. 18FDG produces areas of increased radioactivity (referred to as “hot spots”) where cancer cells are metabolically active.
 - Positron emission tomography is frequently performed after other imaging methods, such as CT or MRI, so it may not replace other imaging tests (anatomical vs. biologic)
- ✓ Agency Concerns:
 - Technology is not new, but the application is changing. Routine use of PET is not authorized due lack of literature on outcomes.
 - A PET Scan policy was brought forward to the Advanced Imaging Management (AIM) work group for Medicaid
 - PET is authorized for diagnosis for Lung and GI cancers to abate risky biopsies
 - PET is authorized when conventional scanning (CT, MRI, plain films) are non-diagnostic
 - PET is authorized if lab test and conventional scanning is not congruent (normal scan with increasing CA125 ovarian cancer)
 - Key concerns:
 - Will this additional method increase benefits when lesser cost screening has known outcomes?

- More expensive/additional test increases costs – what about outcomes?
 - Is the measure of a new test only SN/SP – what about PPV?
 - Is it appropriate to measure PET against CT scan – anatomic vs. biologic?
 - Are there better outcomes or reduced costs for the extra radiation dose?
- ✓ Current State Agencies Policies:
- DSHS allows PET when: there is a Non-diagnostic conventional scan for diagnosis, biopsies, staging/restaging or surveillance
 - UMP allows PET in lymphoma:
 - SURVEILLANCE OF ASYMPTOMATIC PATIENTS AFTER THERAPY FOR MALIGNANCY PET or PET/CT is considered not medically necessary for patients who have completed therapy twelve (12) or more months ago for lymphoma or six (6) or more months ago for all other malignancies unless the patient demonstrates signs, symptoms, laboratory or other objective findings suggestive of recurrence or spread of the original malignancy
 - SCREENING: PET or PET/CT IS NOT COVERED AS A SCREENING TEST (I.E., FOR EVALUATION OF PATIENTS WITHOUT SPECIFIC SIGNS AND SYMPTOMS OF DISEASE).
- ✓ State Agencies Questions:
- Safety: Benefit vs. Harms issues?
 - Do less expensive diagnostics have less risk for radiation exposure?
 - Does the identification of non-specific findings (false positives) lead to unnecessary interventions?
 - Is that a Red Flag for over use of PET?
 - Mode was 1, the mean was 2, and the max per case 19 PET (> 40 CT scans) in 5 year period
 - Effectiveness:
 - Is the evidence of sensitivity, specificity, and reliability enough to make a benefit decision?
 - Can we define when an MRI/CT/Gallium scan vs. PET is needed in a diagnosis, staging/restaging, surveillance?
 - Cost
 - Does routine PET lead to higher cost for unproven outcomes?
 - What is the impact of differential activity in the community (multiple PET and CT Scans per case)?
- ✓ Cost and Utilization for PET and CT/PET by Year:

PEB PET Scans, Costs and Counts for patients diagnosed with Lymphoma 2007-2010

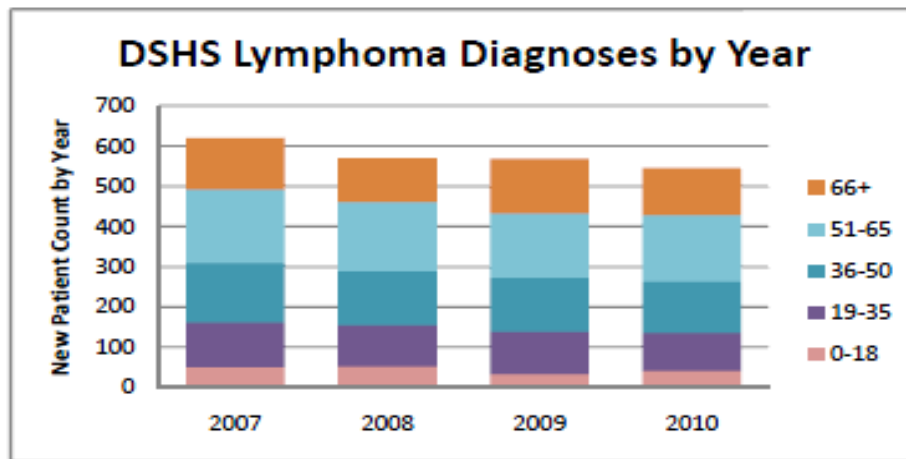
| PEB PET Scans | 2007 | 2008 | 2009 | 2010 | Overall |
|------------------------------|-----------|-----------|-----------|-----------|-------------|
| Members w/PET scans per year | 140 | 168 | 161 | 148 | 409 |
| Scans per year | 221 | 263 | 246 | 235 | 965 |
| Average scans per year** | 1.58 | 1.57 | 1.53 | 1.59 | 2.36 |
| Annual Cost | \$489,106 | \$744,611 | \$605,527 | \$612,285 | \$2,451,529 |
| Average overall cost | \$2,213 | \$2,831 | \$2,461 | \$2,605 | \$2,540 |

| PEB PET Scans | 2007 | 2008 | 2009 | 2010 | Overall |
|----------------------------|---------|---------|---------|---------|---------|
| Average Primary Payer cost | \$3,421 | \$3,876 | \$3,756 | \$3,797 | \$3,735 |

DSHS PET Scans, Costs and Counts for patients diagnosed with Lymphoma 2007 -2010

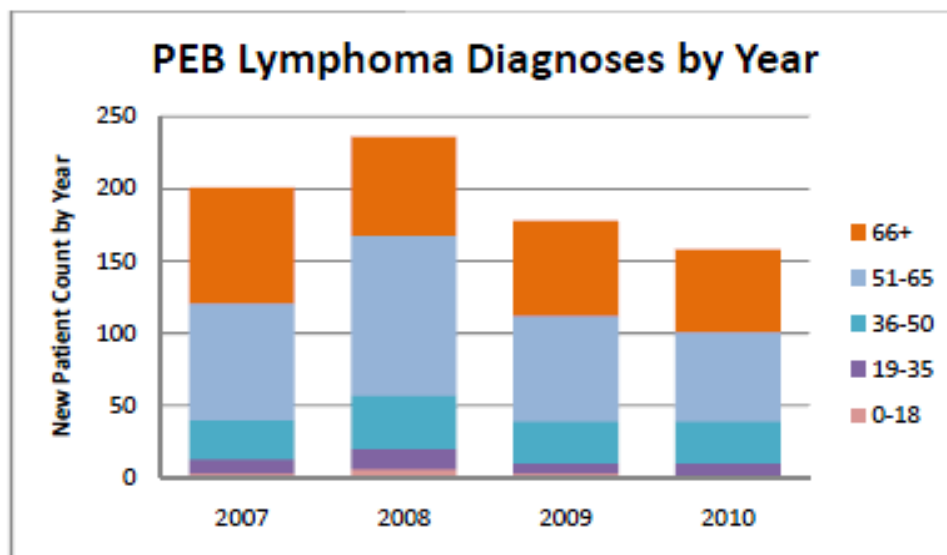
| DSHS PET Scans | 2007 | 2008 | 2009 | 2010 | Overall |
|-------------------------------|-----------|-----------|-----------|----------|-----------|
| Members w/ PET scans per year | 149 | 178 | 192 | 92 | 611 |
| Scans per year | 198 | 240 | 263 | 113 | 814 |
| Average scans per year | 1.33 | 1.35 | 1.37 | 1.23 | 1.33 |
| Annual Cost | \$151,470 | \$196,394 | \$205,563 | \$87,697 | \$641,124 |
| Average scan cost | \$765 | \$818 | \$782 | \$776 | \$788 |

DSHS Lymphoma Diagnoses by Age and Year



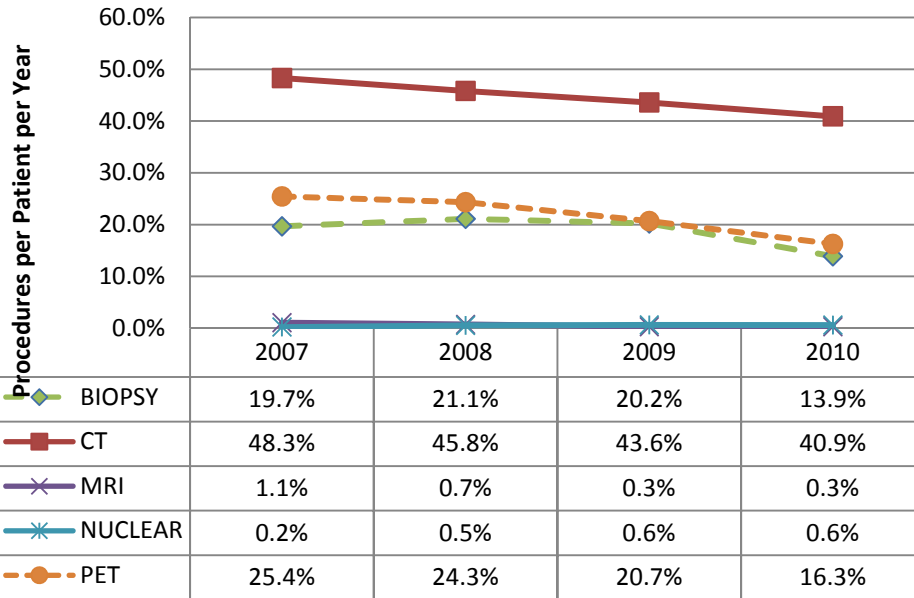
Note: May include new members with a pre-existing condition.

PEB Lymphoma Diagnoses by Age and Year

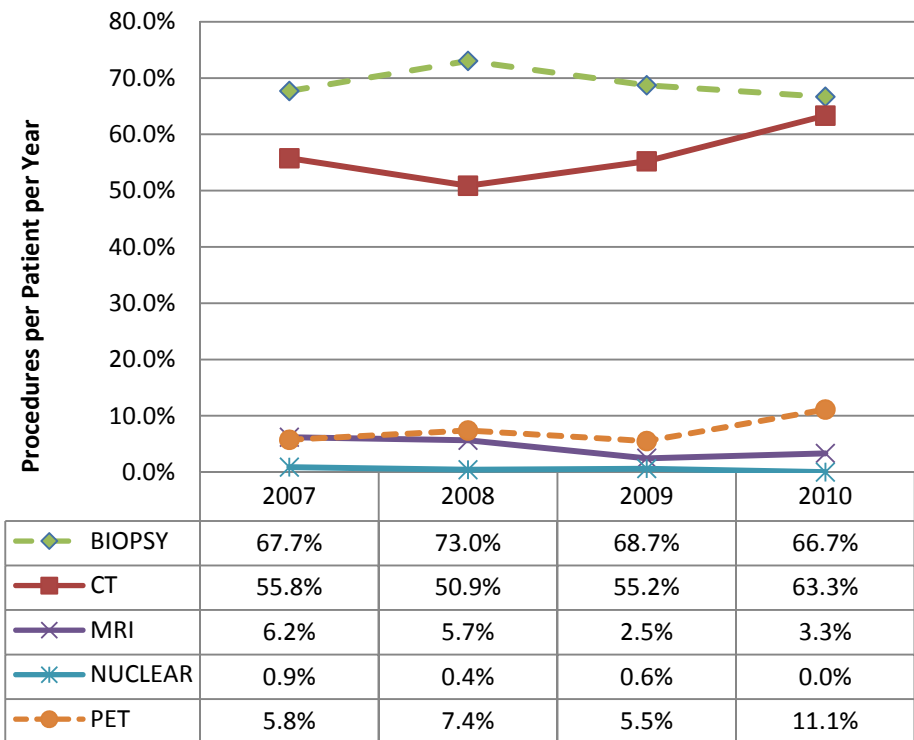


Note: May include new members with a pre-existing condition.

**PEB Lymphoma Patients Post-diagnosis
Percent of Patients by Test Type
(Lymphoma Diagnosis Code Procedures only)**



**PEB Lymphoma Patients Pre-diagnosis
Percent of Patients by Test Type**

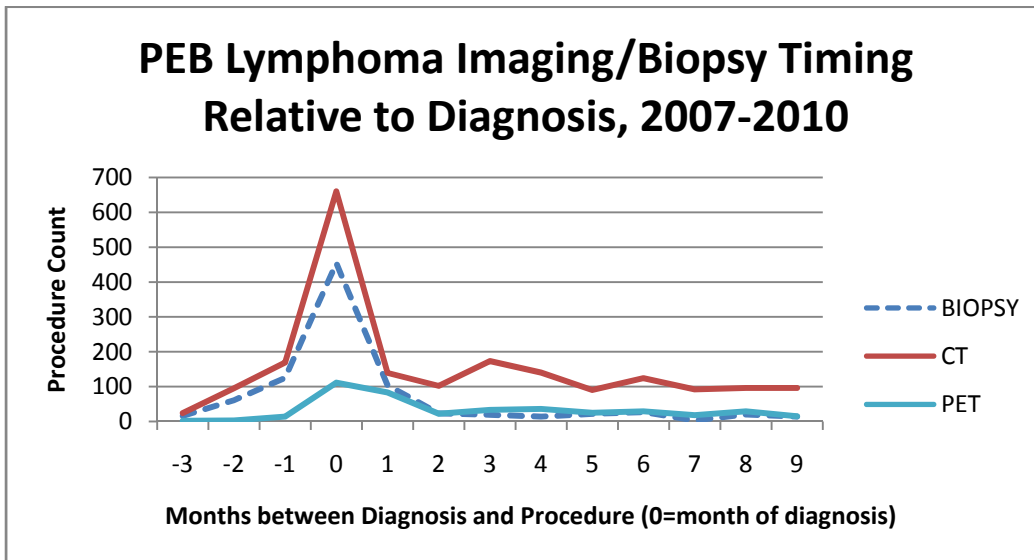


PEB Lymphoma Patient PET Scans Summary Statistics

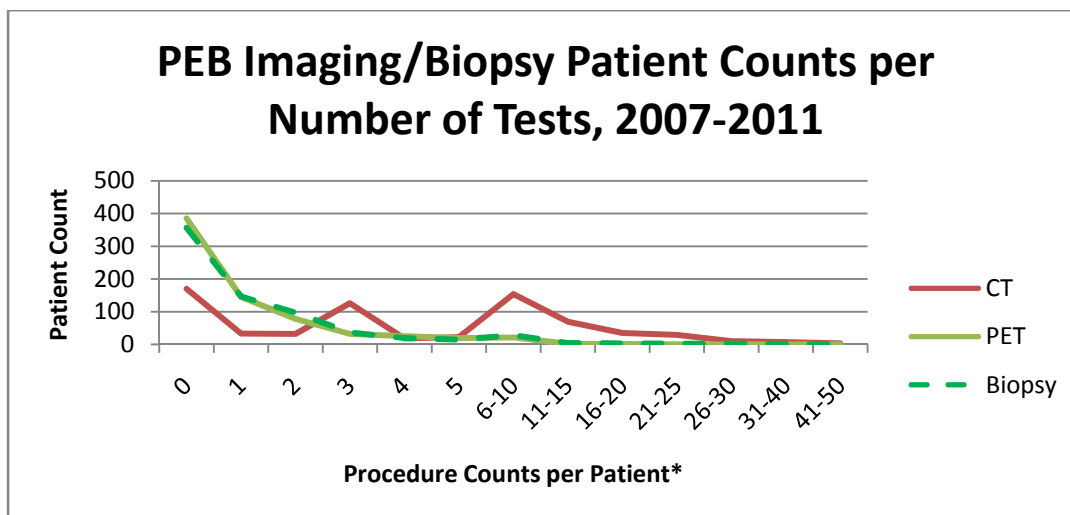
PEB Lymphoma Diagnosis Code PET Scans, Consolidated 2007-2010

| PET Scan in Lymphoma Summary | Hodgkins Lymphoma Patients | Non-Hodgkins Lymphoma Patients | All Lymphoma Patients |
|------------------------------|----------------------------|--------------------------------|-----------------------|
| PET Scan Count | 180 | 613 | 793 |
| Patient Count | 61 | 262 | 323 |
| Average # scans/patient | 2.95 | 2.34 | 2.46 |
| Median scan count | 2 | 2 | 2 |
| Maximum scan count | 15 | 19 | 19 |
| Mode | 1 | 1 | 1 |
| Std Dev | 2.54 | 2.14 | 2.23 |

✓ PEB Lymphoma Visualization Timing Relative to Diagnosis, 2007-2010



✓ PEB Lymphoma Patient Counts by number of Tests, 2007-2011



✓ Hayes Inc. (07)

- Hodgkin's lymphoma (primary staging)
 - **B** and in patients with biopsy-proven recurrent Hodgkin's disease or non-Hodgkin's lymphoma (restaging):
 - **B** - for FDG PET as an adjunct to standard staging techniques, including laparotomy, CT, x-ray, MRI, US, and bone scan, when used as **an alternative to gallium scanning**;
 - **B** - for FDG PET when used as a guide to limited or directed biopsy, imaging, or visualization for evaluation of a particular lesion, when used as **an alternative to gallium scanning**;
 - **C** - for standard staging techniques or a guide to limited or directed staging methods for evaluation of a particular lesion. For PET when used as an early method for monitoring the effects of therapy and altering treatment accordingly:
 - **C** - for patients with Hodgkin's disease or non-Hodgkin's lymphoma when used as a method for tumor grading when the presence of primary or recurrent tumor is known:
 - **C for FDG PET non-Hodgkin's disease.**
 - **C.** for FDG PET with any image analysis method for differentiating lymphomatous from nonmalignant CNS lesions in patients with HIV infection or AIDS:
 - **D** for all other applications
- ✓ Centers for Medicare & Medicaid Services (CMS):
- CMS issued a decision not to make a national coverage decision (NCD) for PET scanning in malignancies. This leaves ultimate coverage decisions on 18FDG PET to local Medicare carriers. In the Decision Memo, CMS (2010) created a two-part framework for analysis of PET use in malignancies—initial treatment strategy and subsequent anti-tumor strategy.(CMS, 2010).
 - For Initial Treatment Strategy, CMS will “nationally” cover lymphoma and other solid malignancies for one FDG PET study for determining the optimal location to perform an invasive biopsy and to determine stage of the tumor
 - Moreover, CMS allows local Medicare contractors to make local decisions for coverage of additional PET scans for therapeutic purposes related to initial treatment strategy.
 - For Subsequent Anti-tumor Treatment Strategy, lymphoma is considered separately from other malignancies. Positron emission tomography is covered without exception.
- ✓ Group Health (Other Centers, Agencies and HTAs)
- Diagnosis: PET results may assist in determining the optimal location to perform an invasive diagnostic procedure. It is not covered for other diagnostic uses or screening (testing patients without symptoms).
 - Staging and re-staging: PET is covered when staging remains in doubt after conventional staging and when clinical management of the patient would differ depending on the stage of lymphoma. Re-staging includes re-staging in the setting of recurrence and restaging following completion of a treatment regimen.
 - Monitoring of therapy: PET is NOT covered.



✓ Pet and Lymphoma: Risks and Benefits

TABLE 2: Radiation Doses From Common Imaging Studies

| Test | Dose (mSv) | Equivalent Period of Background Radiation | Reference |
|---|------------|---|-----------|
| Chest x-ray (standard two views) | 0.06–0.1 | 8–12 days | 13, 14 |
| Mammography | 0.13–0.7 | 16–88 days | 13, 14 |
| Abdomen x-ray | 0.5–0.7 | 62–88 days | 14 |
| Lumbar spine x-rays | 1.8 | 7 months | 14 |
| Head CT | 2.0 | 8 months | 13 |
| Chest CT | 8.0 | 3 years | 13 |
| Abdomen and pelvis CT | 10.0 | 3 years | 13 |
| Virtual colonoscopy | 10.2 | 3 years | 15 |
| Whole-body PET/low dose CT | 8.5–10.3 | 3 years | 16 |
| Whole-body PET/full dose CT | 23.7–26.4 | 8–9 years | 16 |
| Prospective ECG-gated coronary CT angiography | 3.0 | 1 year | 17 |
| Retrospective ECG-gated coronary CT angiography | 11.7–13.0 | 4 years | 17 |
| Coronary angiography (diagnostic) | 4.6–15.8 | 2–5 years | 14 |
| Coronary angiography (with intervention) | 7.5–57.0 | 2–19 years | 14 |

✓ State Agencies Summary View:

- PET in Lymphoma:
 - Improved Sen/SpE but not related to PPV
 - No better than convention Gallium
 - State policy allows PET after conventional scanning is shown non-diagnostic
- Safety Issues not resolved
 - Increased amounts of radiology for questionable outcomes
- Costs Issues
 - Added cost but no outcome data
 - Costs Effectiveness studies – none available
- Non cover for routine diagnostic
 - Cover for biopsies when conventional not adequate
 - For all other reasons (i.e. staging, restaging, surveillance) cover only when conventional scans are non-diagnostic
- Limit the number of scans to no more than 1 per year unless medically justified



Agenda Item: Evidence Review Presentation

Oregon Health & Science University (OHSU) presented an overview of their evidence report on PET scans, full presentation in meeting materials.

- ✓ Background: Lymphoma
 - Heterogeneous group of malignancies involving lymph nodes, bone marrow, spleen and other extra-lymphatic organs. Approximately 74,000 cases in US annually.
 - Hodgkin lymphoma (HL) ~ 13%
 - Non-Hodgkin lymphomas (NHL) ~ 87%
 - HL = classic (95%) and nodular lymphocyte predominant (5%)
 - NHL = B-cell (80%) and T-cell (20%) lymphomas
 - NHL = aggressive (aNHL), indolent (iNHL) and highly aggressive
 - Treatment: Chemotherapy, radiation therapy or combination chemo-radiation. Treatment dependent on cell type and on stage of lymphoma. Primary treatment may result in remission; if lymphoma progresses or recurs, secondary treatment is undertaken.
- ✓ Background: PET
 - Nuclear Medicine test using a positron emitting radionuclide fluorine 18 (¹⁸F)
 - Positrons annihilate with electrons resulting in two gamma photons detected by the scanner
 - ¹⁸F incorporated into a glucose analog (¹⁸FDG) and injected intravenously
 - ¹⁸FDG accumulates in areas of high glucose metabolism
 - PET results in “hot spots” where glucose metabolism is high– e.g. cancer, infection
 - PET uses abnormal glucose metabolism rather than changes in normal anatomy and tissue characteristics (e.g. CT and MRI) to detect cancer
 - **Claim:** PET more sensitive and specific than CT or MRI for detecting viable cancer
 - E.g. residual mass in mediastinum after primary treatment for HL; is it residual fibrous tissue or viable HL?
 - PET images have low spatial resolution
 - PET usually performed with CT in a fusion PET/CT scanner that gives metabolic and high spatial anatomic information synchronously
 - In this report PET and PET/CT are considered as one test
 - Older literature is PET alone; newer literature is PET/CT
- ✓ Background: Washington Experience
 - Lymphoma incidence
 - PEB: 150-230 cases per year
 - DHHS: 530-610 cases per year
 - PET utilization
 - PEB: 220-263 PET scans per year
 - DHHS: 113-263 PET scans per year
 - PET costs
 - PEB: \$2,213-\$2,831 per scan
 - DHHS: \$765-\$818 per scan
- ✓ PICO:
 - **Population:** Adults and children with Hodgkin lymphoma and non-Hodgkin lymphoma.
 - **Intervention:** PET (PET/CT)
 - **Comparator:** MRI, CT, gallium, other imaging methods
 - **Outcomes:** Comparative diagnostic performance; effects on clinical decision making; effects on patient outcomes, safety and costs.
 - screening and initial diagnosis,
 - initial staging,
 - restaging after primary treatment,
 - detection of recurrence,
 - predicting patient outcomes after primary or secondary treatment,
 - monitoring of response to treatment, and
 - surveillance of patients in remission
- ✓ Methods:



- For the WA HTA program, MED core sources searched for SRs, MAs, TAs from 2000 to 2011. MEDLINE search for 2009-2011 included SRs, MAs, TAs and case reports. Search terms *positron emission tomography, PET, lymphoma, Hodgkin disease.*
- Search for relevant clinical practice guidelines using MED core sources and Guidelines.gov databases
- Quality of included systematic review and guidelines rated with standard MED instruments
- State, private payers, and policy websites searched to identify insurance coverage policies
- ✓ Search Results:
 - Core source search yielded 7 SRs and TAs, 3 cost or cost-effectiveness study designs and 6 clinical practice guidelines
 - MEDLINE search yielded 354 citations from which 18 observational studies were included in this report
- ✓ Findings: Evidence presented by Lymphoma Type
 - Hodgkin disease (HL) and aggressive non-Hodgkin disease (aNHL) are combined
 - Indolent non-Hodgkin disease (iNHL) is considered separately
 - Highly aggressive non-Hodgkin disease – no evidence identified
- ✓ Findings: Overview
 - Primary evidence comes from case series
 - Case series considered to be lower strength of evidence than RCTs or cohort studies
 - SOE for most KQs is low to moderate even when SRs are of high quality
 - More evidence for diagnostic accuracy than for clinical effectiveness, safety, cost
 - More evidence for HL and aNHL than for iNHL
- ✓ Accuracy of PET: Screening and Initial Diagnosis
 - No evidence on use of PET for screening or initial diagnosis
 - Diagnosis requires histology; PET cannot eliminate biopsy
 - No guidelines support PET for these indications
- ✓ Initial Staging:
 - Australian MSAC TA (4 SRs)
 - As a separate test, PET has higher combined sensitivity and specificity than CT or gallium

| Test | Sensitivity | Specificity |
|---------|-------------|-------------|
| PET | 88-100% | 90-100% |
| CT | 88% | 80% |
| Gallium | 29-93% | n/a |

- As an incremental test (added to CT), two small series of 33 and 50 patients (from Australian MSAC):
 - PET increased the number of true and false positives (ratio of TP: FP = 3:1).
 - PET occasionally was negative at sites positive on CT; large portion of these negative PET scans were false negatives.
- ✓ Staging after Primary Treatment
 - Routine (Four SRs): Evidence is heterogeneous, mixing HL and aNHL, initial and post-treatment staging CT. PET has higher sensitivity and specificity for detection of HL and aNHL than CT.

| Modality | Sensitivity | Specificity |
|-------------------------------|------------------------|-------------------------|
| CT (Kwee) (mixed HL and aNHL) | 25-100% | 42-67% |
| PET (Kwee) | 71-100% | 57-100% |
| PET/CT (Kwee) | 91-100% | 87-100% |
| PET meta-analysis (Terasawa) | 84% (HL) 72% (aNHL) | 90% (HL) 100% (aNHL) |

- Evaluation of residual mass (3 SRs): Sensitivity and Specificity for PET ranges 40-100%. Both sensitivity and specificity important in clinical decision making about a residual mass. Sensitivities and specificities of 40% may not be sufficiently high for clinical decision making
- ✓ Estimation of Prognosis after Treatment:
 - After primary or secondary treatment responders (PET negative) proceed to surveillance and non-responders (PET positive) proceed to additional treatment



- After **primary** treatment, 2 small case series (99 and 127 patients): PET performed and compared with 2-3 year progression free survival (PFS)

| Modality | 2-3 year PFS if study negative (responder) | 2-3 year PFS if study positive (non-responder) |
|------------|--|--|
| PET (HL) | 94-96 | 19-33 |
| CT (HL) | 90 | 0% |
| PET (aNHL) | 87 | 7% |
| CT (aNHL) | 63% | 0% |

- ✓ Estimation of Prognosis after Secondary Treatment:
 - Two SRs and three case series
 - PET done prior to salvage chemotherapy and stem cell transplant

| Study | Population | Sensitivity | Specificity | Other |
|---------------------|-------------|-------------|-------------|-----------------------|
| Terasawa (SR/MA) | HL and aNHL | 69% | 81% | LR + 3.6 LR - 0.38 |
| Poulou (SR/MA) | HL and aNHL | | | HR + 3.23 |
| Moscowitz (153 pts) | HL | 50% | 84% | HR + 3.4 |
| Dodero (80 pts) | HL and aNHL | 68% | 63% | |
| Qaio (34 pts) | aNHL | 75% | 87% | PPV 86% NPV 76% |

- ✓ Surveillance of Asymptomatic Patients:
 - Surveillance = routine study of patients without symptoms
 - Not the same as re-evaluation of patients with clinical evidence of progression such as progressive symptoms, new or increasing lymphadenopathy or other masses
 - No SRs or RCTs; 5 case series
 - Studies consistently show a high false positive rate for PET scans performed on asymptomatic patients
 - PPVs 23-54%; NPVs 90-100%
 - Clinical symptoms were effective in predicting relapse

- ✓ Monitoring of Treatment during Treatment:
 - PET advocated in mid-cycle of treatment (e.g. after 4 of 8 cycles of chemotherapy)
 - Rationale # 1: if PET can predict non-response in mid-cycle, initial treatment could be terminated and secondary treatment begun, saving the expense and side effects of additional cycles of primary treatment. **Need high PPV or LR + for PET**
 - Rationale # 2: if PET showed response in mid-cycle, *perhaps* no additional treatment needed; *perhaps* stop at 4 cycles. **Need high NPV or low LR - for PET**
 - No evidence to support this rationale
 - One SR/MA and 3 case series

| Study | Population | Sensitivity | Specificity | Other |
|-------------------|-------------------------------|-------------|-------------|---|
| Terasawa (SR/MA) | HL (360 pts) NHL (311 pts) | 81% 78% | 97% 87% | LR+ 28 LR- 0.19 LR+ 5.9 LR- 0.26 |
| Zinzani (91 pts) | aNHL | 82% | 89% | PPV 82% NPV 89% |
| Markova (50 pts) | HL | 75% | 100% | PPV 75% NPV 100% |
| Duhrsen (128 pts) | aNHL | n/a | n/a | PET +, recurrence rate 17% PET -, recurrence rate 3% |

- Studies consistently show higher specificity (87-97%) than sensitivity (78-81%)
- NPVs are higher than PPVs
- LR - are stronger than LR +
- PPV, NPV, LR + and LR - may not be strong enough to change clinical decision making
- ✓ KQ2: Clinical Effectiveness for HL and aNHL



- No evidence on the effect of PET on
 - Reduction of use of other tests
 - Patient survival
 - Quality of life
- Limited evidence of effect of PET on
 - Changes in management
- Changes in clinical management:
- Australian MSAC TA
 - No direct evidence
 - Staging alters clinical decisions
 - Monitoring could alter clinical decisions
- Pommier (case series of 137 patients)
 - 137 HL patients; 124 patients scheduled for radiotherapy had PET:
 - 102 (82%) had no change in plan; 6 (5%) had radiotherapy cancelled; 16 (13%) had radiotherapy plan altered
- ✓ KQ1: Accuracy of PET in Indolent NHL (iNHL)
 - Evidence on iNHL is very heterogeneous— different studies report on different iNHLs which do not necessarily behave similarly; individual case series for each iNHL; no MAs or RCTs; reference standard in these studies often not stated; analyses mix patients and lymphoma sites. Strength of evidence is LOW.
- ✓ Original Diagnosis and Staging:
 - No evidence on diagnosis
 - PET appears to detect additional sites of disease not detected on CT but PET also misses disease sites identified on CT
 - One study (Fueger) reported that PET/CT had higher sensitivity (99%) than the individual components PET (68%) and CT (70%) for detection of lymphoma sites
- ✓ Estimation of Prognosis after Treatment:
 - No SRs, MAs; 2 small case series of 45 and 44 patients
 - PET evidence of nodal activity after treatment correlated with subsequent relapse $p < 0.05$
 - PET had a sensitivity of 100% and specificity of 88% for predicting relapse at one year. PPV = 62%; NPV = 100%
- ✓ KQ2: Changes in Management
 - One case series (74 patients with mantle cell lymphoma)
 - Treating physicians asked for management plan blinded to PET results
 - Management plans before and after PET results
 - No change 7%; small change 59%; medium change 7% and large change 27%
- ✓ KQ3: Differences in sub-populations
 - No evidence for any differences in sub-populations
 - Patient age, gender, patient selection criteria
 - Type of scanning machine, software, training
 - Provider type, setting
 - Health care system type
- ✓ KQ4: Safety of PET in Patients with Lymphoma
 - Australia MSAC considers PET to be safe and not different for lymphoma than for other indications for PET
 - This is an editorial opinion
 - No direct evidence
 - Potential safety issues:
 - Contrast reaction to ^{18}F FDG
 - Glucose analog; no reactions reported
 - Radiation dose significant but patients have a potentially fatal disease
 - Radiation dose considerations more important in HL (mostly younger patients) and in surveillance (multiple PETs in potentially cured patients)
 - Incidental findings: no evidence on rate of incidental findings but a number of false positive PETs reported
- ✓ Radiation Dose
 - PET: 10-30 mSv (~300 CXRs)



- Standard CT: 10-30 mSv (~300 CXRs)
- Low dose CT: 2-10 mSv (~100 CXRs)
- PET/CT: 12-60 mSv (potentially 600 CXRs)
- ACR estimates the additional lifetime risk of fatal cancer from 30 mSv to be “moderate” (risk = 1/1,000 to 1/ 500)
- ✓ KQ5: Costs of PET
 - Evidence is weak
 - Different health delivery systems and costs
 - Australian MSAC (2010). Economic model using PET for staging estimated savings of A \$150-210 per patient with PET
 - 130 HL in Brazil, PET used for staging if CT inconclusive; savings of 1% overall for HL
 - 192 HL in US; PET and CT used for surveillance; US \$100,000 and 147 mSV per recurrence detected
 - 68 HL and aNHL in Switzerland with PET at mid-treatment and again at end of therapy; if PET at mid-treatment was negative, could avoid PET at end of treatment with a savings of 26% on PET costs
- ✓ Guidelines: Six guidelines included in report: CADTH (2010); IHPL(2007); NCCN (2011 and 2011); and ACR (2010 and 2011)
 - Guidelines quality rated as poor (IHPL) to fair (NCCN, ACR) to good (CADTH) based primarily on systematic literature review and author independence

| Guideline | CADTH | NCCN HL | NCCN NHL | Juweid (IHPL) | ACR HL F/U | ACR HL Stage I-II |
|--------------------|----------------------------|---------------|---------------|--|---------------|----------------------|
| Diagnosis | Not addressed | Not addressed | Not addressed | Not addressed | Not addressed | Not addressed |
| Primary staging | Recommend | Recommend | Optional | Recommend | N/A | N/A |
| Secondary staging | Recommend | Recommend | Not recommend | Recommend | N/A | N/A |
| Estimate prognosis | Some reports suggest value | Recommend | Not recommend | Recommend if results will alter management | N/A | N/A |
| Monitor treatment | Not addressed | Not addressed | Not addressed | Not addressed | Not addressed | Not addressed |
| Surveillance | Not recommend | Not recommend | Not recommend | Not recommend | Not recommend | Not recommend |

- ✓ Policy Considerations:
 - Coverage policies for Medicare, Regence Blue Cross, Aetna and Group Health
 - CMS Decision Memo (2010): CMS did NOT issue a national coverage decision
 - CMS (2010) has a new PET framework:
 - Initial treatment strategy: NCD of one PET
 - Subsequent anti-tumor treatment strategy: left to local regional carriers to decide
 - Exception for lymphoma– cover all PET
- ✓ Policy Considerations – Insurance Coverage

| Indication | CMS | Aetna | Blue Cross | GroupHealth |
|--------------------------------|---|--|--|--|
| Diagnosis | Cover to determine optimal location for biopsy | Cover to determine optimal location for biopsy | Cover to determine optimal location for biopsy | Cover to determine optimal location for biopsy |
| Staging and re-staging | Cover one PET for initial staging; subsequent staging unlimited (NCD) | Cover | Cover | Cover |
| Monitoring of treatment | Cover if necessary to determine optimal treatment strategies (NCD) | Not covered | Cover if necessary to determine optimal treatment strategies | Not covered |
| Surveillance | Not addressed | Not covered | Not covered | Not addressed |
| Screening | Not covered | Not addressed | Not covered | Not addressed |

✓ **Summary:**

- Lymphoma is a heterogeneous group of malignancies with varied treatment dependent on cell histology and stage
- The evidence for this report is based on case series rather than RCTs
- Strength of evidence is low to moderate
- PET is used for a number of indications in the evaluation of lymphoma

✓ **Summary – Strength of Evidence:**

- For KQ1 – diagnostic accuracy, there is a moderate amount of low to moderate strength evidence
- For KQ2 – clinical effectiveness, there is very limited, low strength evidence
- For KQ3 – sub-populations and KQ 4 – safety, there is no evidence
- For KQ5 – costs, there is very limited low strength evidence

| PET indication | Overall Evidence | Strength of Evidence | Guidelines Recommendation | Insurance Coverage |
|-------------------------|---|----------------------|---------------------------|--------------------|
| Screening | None | N/A | Against use | No coverage |
| Diagnosis | Not beneficial. One study of 8 patients. | Low | Against use | No coverage |
| Original Staging | For HL and aNHL , PET sensitivity and specificity 88-100% and 90-100%; Sensitivity and specificity for CT 88% and 80%. For iNHL , PET/CT had higher sensitivity (90%) than CT (70%) or PET alone (68%). PET appears to detect additional disease but also miss disease detected by CT. | Moderate Low | For use For use | All cover |

| PET indication | Overall Evidence | Strength of Evidence | Guidelines Recommendation | Insurance Coverage |
|-------------------------|---|----------------------|--|--------------------|
| Re-staging | For HL, PET sensitivity 84% and specificity 90-100%. | Moderate | For use | All cover |
| | For aNHL, PET sensitivity 72% and specificity 100%. | Moderate | | |
| | For iNHL, no evidence | None | | |
| Estimation of Prognosis | For HL and aNHL, PET sensitivity 81%; specificity 97%; PPV 0%, NPV 63%. | Low | For use | All cover |
| | For iNHL, PET sensitivity 100%; specificity 88%; PPV 62%; NPV 100%. | Low | | |
| Monitoring of Treatment | For HL and aNHL, PET PPV 15-80%; NPV 90-100%. | Moderate | For use if part of a clinical trial. Not for routine use | No coverage |
| | For iNHL, no evidence | None | | |
| Surveillance | For HL or aNHL, significant false positive PET scans when used in asymptomatic patients in remission. | Low | Against use | No coverage |
| | For iNHL, no evidence | None | | |

Agenda Item: HTCC PET Scans Discussion and Findings

Dr. Blackmore, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of PET scans 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

The evidence based technology assessment report indicates:

- 1.1 Positron emission tomography (PET) is a diagnostic imaging test using a positron emitting radioactive particle. In PET for cancer, the radioactive particle is currently ¹⁸fluorine (¹⁸F) which is incorporated into a glucose molecule ¹⁸FDG. When injected into the blood stream, ¹⁸FDG preferentially accumulates in areas of high glucose metabolism such as areas of active cancer. The PET scan produces areas of increased radioactivity (referred to as “hot spots”) where cancer cells are metabolically active. Positron emission tomography is frequently performed after other imaging methods, such as CT or MRI, so it may not replace other imaging tests. In current practice, PET is normally performed on a fusion PET/CT scanner which produces PET “hot spot” data and CT anatomic data synchronously. The claim for PET is that the changes in glucose metabolism detected by PET are more sensitive and specific for presence of viable cancer than CT or MRI, which rely on changes in local anatomy and tissue properties.
- 1.2 Lymphoma is a heterogeneous group of lympho-proliferative malignancies involving lymph nodes, bone marrow, spleen and other extra-lymphatic organs that affects approximately 74,000 individuals in the US annually. Lymphoma is divided into Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). In turn, NHL is divided into many sub-types that are usually grouped into aggressive NHL (aNHL) and indolent NHL (iNHL).



- 1.3 It is estimated that 74,000 US individuals will be diagnosed with lymphoma [about 65,500 non-Hodgkin lymphoma (NHL) and 8,500 Hodgkin lymphoma (HL)]. This makes NHL approximately eight times more frequent than HL. Depending on type and stage of lymphoma, five year survival rates are as high as 80 to 90%. Accurate information about diagnosis and staging is important for planning the most appropriate treatment strategy, response to treatment, and monitoring for recurrence. Histopathologic tissue examination is necessary for definitive diagnosis of HL or NHL. A patient's physical symptoms, palpation, biopsy, magnetic resonance imaging (MRI), computed tomography (CT), gallium, and positron emission tomography (PET and PET/CT) can be used to assess patients. Positron emission tomography and PET/CT (collectively PET) are increasingly performed to inform staging, restaging, and estimation of prognosis after treatment and surveillance for recurrence of cancer.
- 1.4 Evidence included in the technology assessment review was obtained through a structured, systematic search of the medical literature; economic studies; and clinical guidelines. MEDLINE search retrieved 354 full citations from which 18 observational studies were included. Core source searched yielded 7 SRs and TAs, 3 cost or cost-effectiveness study designs and 6 clinical practice guidelines.
- 1.5 The evidence based technology assessment report identified six expert treatment guidelines. CMS Decision Memo (2010): CMS did NOT issue a national coverage decision. CMS (2010) has a new PET framework:
 - Initial treatment strategy: NCD of one PET
 - Subsequent anti-tumor treatment strategy: left to local regional carriers to decide
 - Exception for lymphoma – cover all PET
- 1.6 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 indicates that there is limited evidence on safety. Although, there is moderate radiation dose associated with each PET and PET/CT scan performed, lymphoma is a potentially lethal disease. Concern for the effects of radiation may be more important for younger patients and for repeated PET and CT studies during follow-up. The overall strength of evidence is low.
- 2.2 The evidence based technology assessment report indicated that the Australia MSAC (2010) addressed the question of safety of PET. No evidence directly addressed safety of PET in lymphoma. Australia MSAC believed that data on safety for PET for other indications can be reasonably applied to PET for lymphoma. Australia MSAC concludes that PET for lymphoma is safe.
- 2.3 The evidence based technology assessment report indicated that potential safety issues for PET would include contrast reactions, radiation dose levels and incidental findings. The radiopharmaceutical ¹⁸FDG used for PET scanning is an analog of glucose. Intuitively, ¹⁸FDG should be well tolerated as a glucose analog, and no contrast reactions have been noted for ¹⁸FDG. Radiation dose from PET (and PET/CT) is significant. Radiation dose from PET is 10-30 mSv (approximately 300 chest x-ray equivalents). Dose from CT varies depending on whether the CT is a low-dose CT performed to anatomical correlation only or a standard CT. Dosage from standard CT is also 10-30 mSv (also equivalent to approximately 300 chest x-rays). Dosages from PET/CT must be added.

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 Screening and Diagnosis – the evidence based technology assessment report indicated that there is no evidence about the use of PET for either screening of asymptomatic patients or in making a diagnosis of lymphoma. The diagnosis of lymphoma always requires tissue sampling (biopsy) for histological diagnosis.
- 3.2 Original Staging by PET (or PET/CT) Compared with Conventional Staging or as an Incremental Test to Conventional Staging –
 - *Hodgkin and Aggressive Non-Hodgkin Lymphoma (aNHL)*: the evidence based technology assessment report indicated that staging for HL and aNHL is normally performed after diagnosis and before primary treatment in order to determine the extent of disease. Staging is important because the detection of additional sites of HL or aNHL may alter both the stage and the planned treatment. The evidence based technology assessment reported that the Australian MSAC technology assessment *Positron Emission Tomography for Lymphoma* (2010) summarized four systematic reviews (Kwee, 2008; Facey, 2007; Pakos, 2005; Kirby, 2007) that address the use of PET for original staging. These systematic reviews evaluate PET compared to CT and/or to gallium scintigraphy. The Australian MSAC technology assessment also reviews two studies that evaluate PET as an incremental study to conventional staging. When compared to CT or gallium, PET appears to consistently have higher sensitivity and specificity than CT or gallium for staging of HL and aNHL. The sensitivity for PET in detecting HL and aNHL at initial staging ranges from 88-100% compared to sensitivity for CT of 88% and for gallium of 20-93%. Specificity for PET ranges from 90-100% compared to 80% for the specificity of CT. The evidence based technology assessment reported indicated that no RCTs or other study designs were identified for original staging.
 - *Indolent Non-Hodgkin Lymphoma (iNHL)*: The evidence for PET staging is mixed. Positron emission tomography appears to detect additional disease compared to CT in a significant number of patients but also appears to miss disease detected by CT. The series by Fueger (2009) compared PET/CT to PET alone and CT alone and found that PET/CT performs better than either of the comparators. This is not surprising given the evidence from other series that PET and CT both detect disease missed by the other modality. The studies reported here did not clearly state the reference standard. This makes evaluation of the true sensitivity and specificity impossible. The quality of the case series is low and the overall strength of the evidence is low. The evidence for PET staging is mixed. Positron emission tomography appears to detect additional disease compared to CT in a significant number of patients but also appears to miss disease detected by CT. The series by Fueger (2009) compared PET/CT to PET alone and CT alone and found that PET/CT performs better than either of the comparators. This is not surprising given the evidence from other series that PET and CT both detect disease missed by the other modality. The studies reported here did not clearly state the reference standard. This makes evaluation of the true sensitivity and specificity impossible. The quality of the case series is low and the overall strength of the evidence is low. No RCTs were identified. Four case series report on accuracy of PET in original staging of iNHL. Fueger (2009) reported on 45 patients with iNHL who had PET/CT for original staging. Scott (2009) reported on 74 consecutive patients with iNHL who received PET after conventional staging; all 74 patients received PET and 16 patients also had gallium scans. Le Dortz (2010) retrospectively reviewed 45 patients with iNHL



- who underwent initial staging with CT and PET. Bodet-Milin (2010) retrospectively reviewed 45 patients with mantle cell lymphoma (iNHL) who underwent PET in addition to conventional scanning prior to treatment.
- 3.3 Routine Staging after Primary Treatment – the evidence based technology assessment report indicated one scenario for staging after primary treatment is the “routine” evaluation of every patient to evaluate for persistent or non-responsive lymphoma. The evidence for diagnostic accuracy of PET for staging is mixed. Some of the evidence evaluates PET as a substitute for conventional staging and some as an incremental study added to conventional staging. The underlying studies mix HL and aNHL populations for which, on at least one study, PET has different accuracy. The studies often mix initial staging with staging after primary treatment. Positron emission tomography appears to have higher sensitivity and specificity than conventional staging for detection of sites of lymphoma. Positron emission tomography certainly identifies more sites than conventional imaging; this phenomenon is typical for “hot spot” imaging techniques which produce information for the entire body instead of just the areas chosen for imaging (e.g., CT of the chest, abdomen and pelvis). Additional sites identified by PET will include true positive and false positive results. PET appears to perform better for original staging than for staging after primary therapy.
- The evidence based technology assessment report indicated that no RCTs were identified. One small, single center case series reported on PET for staging after primary treatment (Cerci, 2010).
- 3.4 Evaluation of Residual Mass after Primary Treatment – the evidence based technology assessment report indicated no RCTs or other study designs were identified of residual mass after treatment. PET appears to have heterogeneous results in the evaluation of residual mass after completion of primary therapy. Both sensitivity and specificity have wide ranges of 40-100%. Facey (2007) concluded that PET has higher specificity than CT but similar sensitivity. In the evaluation of a residual mass, both sensitivity and specificity have a comparable bearing on further clinical management and sensitivities or specificities of 40% may not yield reliable information for changing treatment decisions. The three systematic reviews are all rated fair to good. The underlying studies are case reports and were noted by systematic review authors to have methodological flaws. Given the heterogeneous results, the strength of the evidence is low.
- 3.5 Estimation of Prognosis after Primary Treatment – the evidence based technology assessment report indicated no RCTs or other study designs were identified. One systematic review based on two case series evaluates the ability of PET at the end of primary treatment to predict subsequent outcome. Positron emission tomography appears to have a reasonable sensitivity but heterogeneous specificity in two studies. It appears to outperform CT in predicting subsequent outcome. The evidence is based on two small case series and overall strength is considered low.
- The evidence based technology assessment indicated that Australia MSAC (2010) reported two case series of 99 and 127 patients that evaluated the ability of PET to distinguish between “responders” and “non-responders”. These two case series compared PET results with 2-3 year progression-free survival (PFS).
- 3.6 Estimation of Prognosis after Secondary Treatment – the evidence based technology assessment report No RCTs were identified. Three case series address the ability of PET to predict relapse or recurrence after salvage treatment (Moskowitz, 2010; Doder, 2010 and Qiao, 2011). The statistics provided in the two systematic reviews and three case series make comparison difficult. It appears that PET has a lower sensitivity and specificity in predicting subsequent outcome after secondary treatment than after primary treatment. Likelihood ratios or hazard ratios of 3-4 and PPV and NPV of around 80% do not provide strong indication of subsequent outcome. As with estimation of prognosis after primary



treatment, it is unclear if sensitivity, specificity and likelihood ratios values given here would alter subsequent management. Although the systematic review and case series are of moderate to good quality, the overall strength of the evidence is low.

- The evidence based technology assessment report indicated two systematic reviews address the ability of PET to predict relapse or recurrence after salvage (secondary) treatment (Terasawa, 2010; Poulou, 2010).
- 3.7 Surveillance of Asymptomatic Patients after Treatment – the evidence based technology assessment report indicated no systematic reviews or technology assessments that address PET in surveillance of patients without symptoms who are in remission after treatment for HL or aNHL. No RCTs were identified either. Five case series evaluate the value of PET during surveillance of patients with HL and aNHL in remission (Goldschmidt, 2011; Lee, 2010; Crocchiolo, 2009; Mocikova, 2010; and Petrausch, 2010). The evidence based technology assessment report indicated that the evidence for the use of PET for routine surveillance of patients in remission is consistent. Positron emission tomography performed on asymptomatic patients has a significant false positive rate. Clinical findings and original stage of HL or aNHL are good predictors of subsequent relapse or recurrence. Positron emission tomography does not appear to have a strong role in surveillance of asymptomatic patients. The evidence consists of five recent case series of poor to fair quality. The overall strength of the evidence is low.
- 3.8 Monitoring of Response to Treatment during Treatment – the evidence based technology assessment report indicated that one systematic review and three case series investigated the ability of PET scan performed mid-cycle during primary treatment to predict subsequent outcome. Pooled sensitivity from Terasawa’s meta-analysis was 81% for HL and 78% for aNHL; specificity was 97% for HL and 87% for aNHL. Results from the three case series are comparable. Results for PPV and NPV from the case series vary from study to study (one study evaluated HL and another aNHL). It is uncertain if the diagnostic efficacy results are strong enough to justify management changes in mid-treatment. The results are internally consistent and overall strength of evidence is considered moderate.
- The evidence based technology assessment report indicated a systematic review by Terasawa (2009) which evaluated the ability of PET to predict disease progression or relapse when performed in mid-cycle of primary treatment for HL or aNHL.
- 3.9 Estimation of Prognosis during or after Treatment – *Indolent Non-Hodgkin Lymphoma (iNHL)*: the evidence based technology assessment report indicated that the evidence is limited to two small case series which suggest that PET findings are reasonably accurate in predicting early relapse of iNHL; a negative PET scan appears to be more valuable than a positive PET. The evidence is considered weak because of the small number of patients included in these case series, and the overall strength of evidence is low. No RCTs were identified.
- 3.10 *Hodgkin and Aggressive Non-Hodgkin Lymphoma (aNHL)*: The evidence based technology assessment reported indicated no evidence was identified for the effect of PET on the reduction of other tests, patient survival or quality of life. There is limited evidence on changes in management. There is limited evidence on the effect of PET on patient management, quality of life or survival. The overall strength of evidence is considered low. *Indolent Non-Hodgkin Lymphoma (iNHL)*: Positron emission tomography appears to have modest impact on clinical decision making. The evidence is based on one small case series and is considered of low strength. No RCTs were identified. Scott (2009) reported on change in management after PET staging in a case series of 74 patients with iNHL.

4. Special Populations

- 4.1 The evidence based technology assessment report indicated that no evidence on special populations was reported.

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 assessment report indicated that the evidence for costs of PET in lymphoma comes primarily from outside the United States. Several of the studies are valued in US dollars, but the medical delivery and payment systems are different than in the US. The evidence should therefore be interpreted with care. The cost data comes primarily from outside the US. The four studies identified use different cost assumptions. The savings from PET are small under any of the cost assumptions studied. The single US study found that routine surveillance imaging cost \$100,000 and had an increased radiation dose of 147 mSv per recurrence detected. The overall strength of evidence is low.
- 5.3 Australia MSAC (2010) identified no published studies that it considers relevant or of sufficient quality to include. The authors performed an economic analysis based on using PET in place of conventional methods for staging. Assuming PET is used, the Australia MSAC estimates a savings of Australian \$150 (8%) per HL patient and Australian \$210 for NHL.
- 5.2 The evidence based technology assessment report identified no RCTs.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

- 6.1 Centers for Medicare and Medicaid Services (CMS) – no NCD policy addressing children.
- The evidence based technology assessment report indicated that in 2010, CMS issued a decision not to make a national coverage decision (NCD) for PET scanning in malignancies. This leaves ultimate coverage decisions on ¹⁸F¹⁸FDG PET to local Medicare carriers. In the Decision Memo, CMS (2010) created a two-part framework for analysis of PET use in malignancies—initial treatment strategy and subsequent anti-tumor strategy.
 - For Initial Treatment Strategy, CMS will “nationally” cover lymphoma and other solid malignancies for one FDG PET study for determining the optimal location to perform an invasive biopsy and to determine stage of the tumor. Moreover, CMS allows local Medicare contractors to make local decisions for coverage of additional PET scans for therapeutic purposes related to initial treatment strategy.
 - For Subsequent Anti-tumor Treatment Strategy, lymphoma is considered separately from other malignancies. Positron emission tomography is covered “nationally” without exception.
- 6.2 Guidelines – the evidence based technology assessment report identified a total of nine guidelines in the core source search, and no additional guidelines were identified in the MEDLINE search. Of the original nine guidelines, four were excluded because they did not address PET scanning. The remaining guidelines include one from the *International Harmonization Project in Lymphoma (IHPL)* and two each from the *National Comprehensive Cancer Network (NCCN)* and the *American College of Radiology (ACR)*. The guidelines from NCCN and ACR were rated as fair quality and the guideline from IHPL was rated as poor quality. Poor quality ratings are primarily the result of undisclosed literature search methods for cited literature and for potential conflicts of interest of authors.



- The evidence based technology assessment report indicated that the NCCN (2011a; 2011b) guidelines recommend the use of PET for initial staging of HL and aNHL. The NCCN recommends PET for staging in iNHL as optional but potentially useful in iNHL that appears to be localized and if concern exists about histological transformation. The NCCN guidelines recommend PET for evaluation of residual mass after treatment. The NCCN and IHPL (Juweid, 2007) guidelines recommend use of PET after treatment to determine prognosis. The IHPL guideline states that PET should only be performed in mid-cycle of treatment *if the findings will alter management*. The ACR (2010, 2011) guidelines caution that *changes in treatment based on PET findings should only be performed as part of a clinical trial*. Guidelines from NCCN and ACR recommend against the use of PET for routine surveillance. The ACR guidelines add that PET may be helpful in surveillance patients with clinical findings suspicious for relapse.
- The evidence based technology assessment report indicated that the guidelines recommend the use of PET for initial staging of HL and aNHL. The routine use of PET to predict subsequent outcome is not recommended by the guidelines. Guidelines recommend against PET in surveillance of asymptomatic patients in remission after primary or secondary treatment. Guidelines are congruent with the evidence gathered for this report.

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 PET scans has been collected and summarized.

- 1.1. The evidence review summarized the evidence on the safety and efficacy of PET for Lymphoma. Lymphoma is divided into Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL) based on the histological pattern of the malignancy. Hodgkin lymphoma is an uncommon malignancy involving lymph nodes and the lymphatic system.
- 1.2. The evidence review summarized that since 2011, PET is usually performed on a combined PET-CT scanner where both the radioactive PET data and high spatial resolution CD data are recorded at the same time.
- 1.3. The evidence review summarized that false negative PET scans can result from areas of cancer that may be too small or too metabolically inactive to accumulate enough ¹⁸FDG to be detected by the PET scan.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that PET is unproven to be equally or more safe than other conventional treatments. Key factors to the committee's conclusion included:

- 2.1. The committee unanimously agreed that the safety of PET is unproven.
- 2.2. A majority of the committee agreed that the PET scans can lead to: allergic reactions; false positives, which could lead to additional diagnostic tests; and the high radiation levels were a concern. The committee agreed with what the ACR guidelines reported on safety.

3. Is it effective?

The committee concludes that the comprehensive evidence shows that PET is a more effective treatment than conventional alternatives. Key factors to the committee's conclusion included:

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- 3.1. The committee agreed that limited evidence was available in the use of PET for additional prognostic information.
- 3.2. The committee agreed that sufficient evidence exists to conclude that PET is a more effective treatment compared to conventional treatments.
 - The OHSU evidence report found moderate quality evidence that PET may be more sensitive and specific for HL and NHL at initial staging and planning of primary treatment.
 - The report found low evidence of potential significant false positive in PET scans for HL and NHL when used for surveillance.

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 evidence based technology assessment indicated that no evidence on special populations was reported.

5. Is it cost-effective?

The committee concludes that the PET is unproven to being more cost-effective than conventional alternatives; agreeing with the comprehensive evidence review that no evidence based conclusions about cost effectiveness can be drawn.

- 5.1. The evidence report adequately summarized the very low quality evidence on cost which helped the committee conclude that PET is not a cost effective treatment.

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 concluded that the current evidence on Positron Emission Tomography (PET) scans for Lymphoma demonstrates that there is sufficient evidence to cover with conditions PET scans for Lymphoma. 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. Based on these findings, the committee voted to cover with conditions Positron Emission Tomography (PET) scans for Lymphoma.

Positron Emission Tomography (PET) Scans for Lymphoma 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.

Positron Emission Tomography (PET) Scans for Lymphoma --

Is there sufficient evidence under some or all situations that PET scans for Lymphoma are:

| | Unproven (no) | Equivalent (yes) | Less (yes) | More (yes) |
|-----------------------------------|--------------------------|-----------------------------|-----------------------|-----------------------|
| Effective | 0 | 2 | 0 | 9 |
| Safe | 8 | 2 | 1 | 0 |
| Cost-effective Overall | 11 | 0 | 0 | 0 |

Positron Emission Tomography (PET) Scans for Lymphoma 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 |
| Positron Emission Tomography (PET) Scans for Lymphoma | 0 | 1 | 10 |

- Action: The committee Chair directed HTA staff to prepare a Findings and Decision document on Positron Emission Tomography (PET) Scans for Lymphoma reflective of the majority vote for final approval at the next public meeting.
- ✓ *Limitations of Coverage:* Based on the evidence about the technologies’ safety, efficacy, and cost-effectiveness, Positron Emission Tomography (PET) Scans for Lymphoma is a covered benefit when all of the following conditions are met:
 - Coverage of a single scan for initial treatment planning;
 - Coverage for additional scans for restaging with clinical suspicion of disease progression or treatment failure subject to agency approval; and
 - No coverage for routine surveillance

The committee discussed Clinical guidelines and Medicare decision, and their coverage determinations are consistent with the clinical guidelines and Medicare decision. The committee found that the evidence review 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 addressed or transparent in clinical guidelines.



Agenda Item: Femoroacetabular Impingement Syndrome (FAI) 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 the FAI review.
- ✓ Staff welcomed, per HTCC request, an invited clinical expert, Dr. Paul Manner, Orthopaedics and Sports Medicine clinician. Dr. Manner prepared a COI and listed no conflicts.

Agenda Item: Public Comments

The Chair called for public comments.

- ✓ Scheduled Public Comments: Three individual stakeholders requested scheduled time for public comments. The stakeholders submitted their presentation and conflict of interest for the committee's consideration prior to the public meeting. All materials and their conflict of interest were included in the meeting materials.
 - Paul Just, PharmD, BCPS, Healthcare Economics, Director, Smith & Nephew, provided comment in support of FAI. Dr. Just stated that Fai is a rapidly evolving science so period differences exist in the published literature relative to state-of-the-art management approaches. Stated that failure to cover FAI would be a disservice to Washington state residents. Lastly, commented on errors he felt were still apparent on the evidence based technology assessment report.
 - Phil Downer, MD, Orthopedic Specialists of Seattle, Proliance Surgeons, provided comment in support of FAI based on hip preservation and avoiding the replacement of the hip being their ultimate goal.
 - Carlos Guanache, MD, paid Smith & Nephew consultant, provided comment in support of FAI. Has conducted hip arthroscopy surgery on thousands of patients. Believes that FAI is no different than treating a shoulder or knee injury. Agrees that hip arthroscopy is not a form of treatment for Osteoarthritis; however, believes that patients would still have better outcomes. Lastly, disagreed that Spectrum stated that no FAI codes were available.
- ✓ Open Public Comments: No individuals provided comments during the open portion.

Agenda Item: Femoroacetabular Impingement Syndrome (FAI) – Agency Data

Dr. Steve Hammond, Department of Corrections, presented to the committee the agency utilization and outcomes for FAI. Full PowerPoint slides in meeting materials.

- ✓ Hip Surgery for FAI Background: Femoroacetabular Impingement (FAI) syndrome has been described in the last 10-20 years. The diagnosis relies largely on physical exam findings and what are often subtle radiographic imaging findings, but there is no standard case definition. FAI is believed to be a cause of pain and limitation of function in relatively young people, including athletes. Surgical intervention is believed by proponents to be superior to non-surgical management – modifies anatomic features thought to cause the syndrome; purported to improve pain and function and purported to decrease risk for development of osteoarthritis (OA) of the hip.
- ✓ Agency Concerns:

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- Safety Concerns (Medium): Young age of patients; long-term benefits and harms unknown. Risk of surgical procedure: re-operation, heterotopic ossification and nerve injury.
 - Efficacy Concerns (High): Evidence for short-term efficacy – improved pain and function? Evidence for long-term efficacy – reduced risk for hip OA? Uncertain case definition.
 - Cost Concerns (Medium): Weak evidence for efficacy, so potentially not cost-effective. Potential for over-utilization due to case definition uncertainty and difficulty identifying cases from billing data. Some evidence for increasing utilization.
- ✓ Coverage Overview:
- DSHS: No formal coverage/non-coverage, no restrictions
 - 2007-2010 PEB: No formal coverage/non-coverage, no restrictions. Payment denied as experimental, paid on appeal.
 - 2011 PEB/Regence policy: Post or pre-op review; Xray or MRI showing cam or pincer angle within specified range; failed conservative management; no concurrent diagnosis of osteoarthritis.
 - L&I: No formal coverage/non-coverage, no restrictions. All surgeries require prior authorization
- ✓ Estimated Utilization Cost – All Agencies:

| Estimated FAI Hip Surgeries , Day of Surgery Costs, 2007-2010 | | | | | |
|---|------------------|------------------|------------------|------------------|--------------------|
| Calendar Year | 2007 | 2008 | 2009 | 2010 | 4 Year Total |
| PEB | \$61,626 | \$96,653 | \$225,815 | \$119,138 | \$503,232 |
| DSHS | \$27,914 | \$43,670 | \$94,995 | \$131,354 | \$297,932 |
| L&I | \$166,204 | \$345,206 | \$388,364 | \$553,039 | \$1,452,813 |
| Total | \$255,744 | \$485,529 | \$709,174 | \$803,531 | \$2,253,977 |

- ✓ Case Cost Examples:

| Year | Member Number | Paid Per Surgery Date |
|--------------------|---------------|-----------------------|
| 2008 | 1 | \$4,103 |
| | 2 | \$4,103 |
| | 3 | \$14,533 |
| | 4 | \$4,103 |
| | 5 | \$3,888 |
| | 6 | \$6,800 |
| 2009 | 7 | \$11,222 |
| | 8 | \$11,896 |
| 2010 | 9 | \$5,307 |
| | 10 | \$6,882 |
| | 11a | \$8,448 |
| | 11b | \$11,174 |
| Grand Total | | \$95,470 |

- ✓ Case Examples, Diagnosis Coding, Gender and Age Distribution



| Diagnosis code Description | Member Count | Total Paid |
|--|--------------|-----------------|
| ARTICULAR CARTILAGE DISORDER, PELVIC REGION AND THIGH | 9 | \$32,522 |
| CHONDROMALACIA | 1 | \$8,982 |
| ENTHESOPATHY OF HIP REGION | 1 | \$10,039 |
| OTHER JOINT DERANGEMENT, NOT ELSEWHERE CLASSIFIED, PELVIC REGION AND THIGH | 8 | \$28,080 |
| OTHER SYNOVITIS AND TENOSYNOVITIS | 1 | \$4,601 |
| SPRAIN AND STRAIN OF OTHER SPECIFIED SITES OF HIP AND THIGH | 1 | \$11,246 |
| Grand Total | | \$95,470 |

| Gender/Age Group | Member Count |
|------------------|--------------|
| F | |
| 19-35 | 3 |
| 36-50 | 5 |
| 51-65 | 1 |
| Total | 9 |
| M | |
| 19-35 | 1 |
| 51-65 | 1 |
| Total | 2 |
| Total | 11 |

✓ Case Example:

- Right hip pain following fall injury. Conservative care, injections tried for 1.5 yrs. Negative MR arthrogram of right hip and pelvis. No evidence of any significant labral pathology. No significant degenerative changes are seen (radiologist). Clinical and radiographic FAI + labral tear (surgeon). Arthroscopic surgery: labral repair, osteoplasty and chondroplasty of femoral head and neck. 7 months post surgery for FAI and labral tear symptoms not improved. Symptoms ongoing at 14 months post surgery.

✓ Summary:

- There is no sufficiently reliable method of diagnosing FAI
- There is inadequate evidence that FAI causes pain, decreased function, or accelerated osteoarthritis
- There is no evidence that surgical intervention for FAI is more efficacious than non-surgical intervention
- There is no evidence that surgical intervention for FAI reduces risk for long-term OA of the hip
- Claims of short-term benefits of surgical intervention for FAI are based on uncontrolled studies (case series)
- Safety of surgical intervention for FAI is in question; heterotopic bone formation and nerve injury have been reported in significant numbers of patients

✓ AMDG Considerations: Based on the available evidence and agency experience the AMDG recommends: Non-coverage of surgical intervention for FAI syndrome.

- Case definition of FAI syndrome is imprecise
- Evidence of efficacy of surgical intervention for short-term benefit is very weak and for long-term benefit does not exist
- There are significant safety concerns related to surgical intervention for FAI syndrome
- There is no evidence to demonstrate cost-effectiveness of surgical intervention for FAI syndrome

Agenda Item: Evidence Review Presentation

Spectrum Research presented an overview of their evidence report on FAI. A full set of slides and information is included in the meeting materials.

- ✓ Background: Recent diagnosis in primarily younger, active individuals and athletes. Often presenting with groin/hip pain, limited hip motion and limitation to activities.
- ✓ Concept: Abnormal contact between the proximal femur and acetabulum, particularly during flexion and internal rotation. Due to minor morphological hip abnormalities. Thought to result in labrum tears, chondral lesions, and progressive osteoarthritis (OA).
- ✓ Classification:
 - Cam-type impingement: Non-spherical femoral head or abnormality at the head-neck junction. Results in increased femoral head radius leading to abnormal contact with the acetabular rim in full flexion.
 - Pincer-type impingement: Functionally deep or retroverted acetabulum. Results in over coverage of the femoral head (relative anterior, focal anterior, or global over coverage).
- ✓ Treatments:
 - Non-operative: Activity modification; NSAIDS; Pelvic postural training; Physical Therapy (?)
 - Surgery: Arthroscopy; Open dislocation of the hip; Arthroscopy combined with a mini-open approach
 - Purposes of Surgery: (1) to remove abnormal outgrowths of bone and damaged cartilage; (2) to reshape femoral neck (CAM) for sufficient clearance with acetabulum and (3) reduce pain & slow progression of OA.
- ✓ However...Ambiguity about: The causes of hip pain; natural history of FAI; relationship of FAI to OA; uncertain case-definition of FAI; uncertain patient selection criterion for surgical procedures and/or questions regarding efficacy/effectiveness, safety and cost effectiveness of surgery for FAI.
- ✓ FAI → Hip Osteoarthritis? Inference based on cross-sectional associations between abnormal hip morphology and OA. Example: Gosvig et al 2010 - deep acetabular socket and pistol grip deformity associated with an increase risk hip OA (RR = 2.2 and 2.4).
- ✓ However, one recent longitudinal study suggests otherwise: Hartofilakidis et al 2011: followed 96 asymptomatic hips with 1 or more morphological features associated with FAI. F/U = 18 years, mean age: 49 years (16-65). OA prevalence: 18%. Authors' conclusion: "a substantial proportion of hips with femoroacetabular impingement may not develop osteoarthritis in the long-term" .
- ✓ Furthermore: Radiographic findings suggestive of FAI are common in healthy asymptomatic young adults, especially males.

| <i>N=2060</i> | <i>Cam-type deformity</i> | <i>Pincer-type deformity</i> |
|---------------|---------------------------|------------------------------|
| Males | 35% | 34% |
| Females | 10% | 17% |

- ✓ Reichenbach et al 2010 selected a random sample of 244 asymptomatic males undergoing conscription for the Swiss Army. 73% had MRI evidence of a cam-type deformity (grade 1, 2 or 3). 24% had evidence of grade 2 or 3.
- ✓ Hack et al 2010 had 200 asymptomatic volunteers from among Canadian hospital workers and medical students.

| | <i>Cam-type deformity</i> |
|----------|---------------------------|
| Males | 25% |
| Females | 5% |
| | |
| IR ≤ 20° | 25% |
| IR ≥ 20° | 5% |



- ✓ Kang et al 2010 – 39% of asymptomatic hips had 1 or more: Acetabular retroversion; crossover sign; coxa profunda; abnormal alpha angle; or abnormal head-neck offset. 74% had aspherical femoral head in at least one plane.
- ✓ Publications Included: Key Question #1 = 11; Key Question #2 = 6; Key Question #3-5 = 46; Key Question #6 = 0.
- ✓ Key Question #1: Case Definition – significant numbers of publications describing various clinical and imaging criteria: groin pain associated with sitting, walking, or athletic activities; reduced ROM; positive impingement/FAIR/FABER test; and/or one or more imaging findings suggestive of morphological abnormalities.
 - Strategy to Answer Question: (1) Inclusion/exclusion criteria from clinical trials and (2) Validity studies assessing the “diagnosis” of FAI using symptoms, physical exam and imaging results.
 - Strategy 1 – Inclusion / Exclusion Criteria: (step 1) RCTs = 0; (step 2) Prospective non-randomized comparative studies = 0; (step 3) Prospective case-series = 7; (step 4) Prospective case-series with inclusion/exclusion criteria = 4.

| | Horisberger et al 2010 | Philippon et al 2010 | Fletcher et al 2011 | Stahelin et al 2008 |
|---------------------------|---|---|-----------------------------------|---------------------------|
| INCLUSION CRITERIA | | | | |
| Pain | “symptomatic” | yes, preventing hockey play | yes, groin, buttock or trochanter | no |
| Length of pain | no | no | ≥6 months | no |
| Failed non-op treatment | no | no | yes | no |
| + impingement | yes | yes | yes | yes |
| Type of FAI | cam or mixed | cam, pincer or mixed | not stated | cam only |
| + imaging sign | yes, osseous bump, α -angle >50° | <u>cam</u> : abnormal head-neck junction AND α -angle >55° <u>pincer</u> : coxa profunda or protrusion OR acetabular retroversion | yes, unspecified | yes, α -angle >50° |
| Limited ROM | yes | no | no | no |
| EXCLUSION CRITERIA | | | | |
| Osteoarthritis | Tönnis grade III | no | Tönnis grade II or III | Tönnis grade III |
| Previous surgery | yes | no | no | yes |
| Precedent trauma | yes | no | no | no |

- ✓ Strategy 2: Validity of Diagnosis Using Clinical Exam, Tests or Imaging

| | Sensitivity | Specificity | Additional measurements |
|---|---------------------|---------------------|--|
| Clinical exam (Martin et al) | | | % agreement: 65% (6 surgeons) |
| Impingement test (Lohan et al) | 76.9% | 87.2% | PPV: 85.7% NPV: 79.1% |
| α -angle MR arthrography (Lohan et al) | 39.3% (3 observers) | 70.1% (3 observers) | PPV: 54.7% (3 observers) NPV: 53.5% (3 observers) |

Draft Version Not Officially Adopted

✓ Key Question 1: Reliability –

| | Intraobserver reliability (ICC or k) | Interobserver reliability (ICC or k) |
|---------------------------------|---|---|
| Clinical exam | | |
| Impingement test | | 0.58 |
| Imaging diagnosis | | |
| “FAI”, “dysplasia”, or “normal” | 0.61 | 0.80 |
| Imaging | | |
| α -angle | 0.60 - 0.88 | 0.52 - 0.95 |
| head-neck offset | 0.43 – 0.73 | 0.19 - 0.24 |
| pistol grip deformity | 0.65 | 0.65 |
| focal prominence | 0.65 | 0.84 |
| head sphericity | 0.55-60 | 0.41 - 0.46 |
| flattening of the femoral head | 0.66 | 0.76 |
| crossover sign | 0.46 – 0.70 | 0.39 |
| posterior wall sign | 0.55 – 0.95 | 0.63 |
| ischial spine sign | 0.58 – 0.90 | 0.54 |
| excessive acetabular coverage | 0.49 – 0.71 | 0.75 |
| acetabular depth | 0.61 | 0.39 |
| acetabular inclination | 0.73 | 0.64 |
| pelvic rotation | 0.57 | 0.21 |

✓ Summary KQ 1 – Case Definition:

- The most consistent case definition of FAI (cam or mixed) as defined by inclusion/exclusion criteria: hip/groin pain; positive clinical impingement test; α -angle >50-55°.
- No evidence that the diagnosis of FAI can be obtained from clinical exam alone. Impingement sign – (one study, prevalence = 50%).
 - PPV: 86% NPV: 79%.
 - Reliability: only moderate
- Even though the α -angle showed moderate to high interobserver reliability, it had poor diagnostic value. Other imaging tests had variable degrees of reliability, but no others were tested for diagnostic validity.
 - Level of Evidence: Very low – due to lack of study quality, quantity and consistency of results.

✓ Key Question 2: Treatment Outcomes –

| Instrument | Validity | | | Reliability | | MCID |
|-----------------|----------|-----------|-----------|----------------------|-----------------|------|
| | Content | Criterion | Construct | Internal consistency | Reproducibility | |
| HOS/HOS-D | – | NR | + | + | +/- | + |
| 12-item m-WOMAC | +/- | NR | +/- | +/- | NR | NR |
| NAHS | + | + | + | +/- | +/- | NR |

✓ Summary KQ2 – Outcomes:

- Validity: only one (NAHS) of the three instruments was adequately tested for validity. Reliability was inadequately tested for all three outcome measures. The MCID was defined to be 9 points for the ADL subscale and 6 points for the sports subscale of the HOS-D in FAI patients.



- Level of Evidence: Very low – due to lack of study quality, quantity and consistency of results

- ✓ Key Question 3: Effectiveness of FAI Surgery –
 - No RCTs
 - 5 retrospective comparative studies:
 - Conservative vs. FAI surgery vs. THA (1 study)
 - Labral debridement vs. labral refixation (2 studies using historical controls)
 - No Osteoplasty vs. osteoplasty (2 studies using historical controls)
- ✓ KQ3: Comparative Effectiveness – Non-operative vs. open FAI vs. THA:

| Author | Outcome (F/U 1.8 years) | Result No. of cases (%) | | |
|---------------|----------------------------|----------------------------|---------------------|----------------|
| | | Non-operative (n = 9) | Open FAI (n = 6) | THA (n = 2) |
| Jager 2004 | Pain free | 0 (0) | 6 (100) | 2 (100) |
| | Return to work/sports | 6 (67) | 6 (100) | 2 (100) |

- ✓ KQ3: Comparative Effectiveness – Debridement vs. refixation, labrum tear

| Author | Outcome | Results | | F/U (years) |
|------------------|---|---------------------------------------|--|----------------|
| | | Debridement | Refixation | |
| Larson 2009 | Failure* Conversion to THA MHHS (% improvement) VAS (0-10) (% improvement) | <u>N = 34</u> 11.1% 0% 36.8% | <u>N = 37</u> 7.7% 2.6% 49.7% | 1.6 |
| Espinosa 2006 | Merle d'Aubigne Pain score (mean change score, % change) | <u>N = 25</u> 186% | <u>N = 35</u> 273% | 2.0 |

*Failure definition: Modified Harris Hip Score < 70, subsequent debridement of a hip that had undergone labral refixation, or conversion to THA

- ✓ KQ3: Comparative Effectiveness – no osteoplasty vs. osteoplasty

| Author | Outcome | Results | | F/U (years) |
|------------------|--|-----------------------------------|-------------------------------------|----------------|
| | | No Osteoplasty | Osteoplasty | |
| Bardakos 2008 | MHHS (% change) | <u>N = 47</u> 40% | <u>N = 24</u> 41% | > 1 |
| Nepple 2009 | MHHS (% change) Failure* Conversion to THA | <u>N = 23</u> 39% 22% 9% | <u>N = 25</u> 40% 0% 0 (0) | 2.0 |

*Failure definition: Modified Harris Hip Score < 70 or need for additional surgery



✓ KQ3: Case-Series:

| Outcome | Arthroscopy | | Open Dislocation | | Mini-open | |
|------------------|--------------------|-------------------|--------------------|-------------------|--------------------|-------------------|
| | No. studies (hips) | Risk, % (95% CI) | No. studies (hips) | Risk, % (95% CI) | No. studies (hips) | Risk, % (95% CI) |
| THA conversion | 9 (N=875) | 4.7 (3.5, 6.3) | 5 (N=204) | 8.3 (5.3, 12.9) | 5 (N=226) | 6.2 (3.7, 10.1) |
| OAProgression | 3 (N=168) | 2.4 (0.9, 5.9) | 2 (N=115) | 23.5 (16.7, 32.0) | 3 (N=157) | 8.9 (5.4, 14.4) |
| Pt. Satisfaction | 3 (N=201) | 82.1 (76.2, 86.8) | 1 (N=34) | 82.4 (66.5, 91.7) | 1 (N=33) | 90.9 (76.4, 96.9) |

| Outcome | Arthroscopy | | Open Dislocation | | Mini-open | |
|-----------|--------------------|---------------|--------------------|---------------|--------------------|---------------|
| | No. studies (hips) | % mean change | No. studies (hips) | % mean change | No. studies (hips) | % mean change |
| HOS (ADL) | 1 (N=112) | 25.4 | | | | |
| NAHS | 6 (N=288) | 44.2 | | | 1 (N=41) | 20.1 |
| WOMAC | 3 (N=80) | 29.9 | 1 (N=34) | 33.0 | | |
| HHS | 4 (N=482) | 32.2 | 2 (N=108) | 33.9 | 1 (N=14) | 19.3 |

- ✓ KQ3: Summary – Efficacy: Level of Evidence – no data available
- ✓ KQ3: Summary – Effectiveness:
 - Short term (≤5 years) – no good evidence that one treatment resulted in better outcomes than another.
 - Surgery versus no surgery
 - Labral debridement versus refixation
 - Osteoplasty versus no osteoplasty
 - Several case series report improvement in pain, function, satisfaction and return to activities following FAI surgery
 - Unknown if improvement is a result of surgery, postop rehab, change in activity, or placebo
 - Level of Evidence: Very low for short-term effectiveness due to lack of study quality, quantity
 - Long term (≥ 10 years) – level of evidence = no data available
- ✓ Key Question 4: Safety –



| Complication | Arthroscopy | | | Open Dislocation | | | Mini-Open | | |
|--------------------------|-------------|------|-----|------------------|------|------|-----------|------|------|
| | Studies | Hips | % | Studies | Hips | % | Studies | Hips | % |
| Reoperation | 14 | 1263 | 3.8 | 7 | 180 | 4.4 | 6 | 334 | 8.7 |
| Head-neck fx | 11 | 688 | 0.2 | 5 | 227 | 0 | 3 | 175 | 0.6 |
| AVN | 8 | 366 | 0 | 6 | 173 | 0 | 2 | 217 | 0 |
| Osteonecrosis | 5 | 304 | 0 | 6 | 227 | 0 | 3 | 110 | 0 |
| Trochanteric nonunion | 4 | 121 | 0 | 5 | 202 | 2.0 | 2 | 134 | 0 |
| Heterotopic ossification | 11 | 1319 | 1.7 | 5 | 168 | 6.0 | 5 | 327 | 3.4 |
| DVT/PE | 8 | 607 | 0 | 4 | 131 | 0 | 1 | 41 | 2.4 |
| Neurological | 15 | 1431 | 1.2 | 5 | 227 | 0 | 5 | 243 | 22.2 |
| Infection | 12 | 1148 | 0.3 | 5 | 139 | 0 | 3 | 258 | 1.2 |
| Other | 3 | 236 | 1.7 | 2 | 85 | 12.9 | 1 | 117 | 29.1 |

- ✓ KQ4: Summary:
 - Reoperation (other than THA conversion) occurred in 4% (arthroscopy and open dislocation) and 9% of the patients (mini-open)
 - There was only one reported head-neck fracture (0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion
 - HO occurred in 2 to 3% of those receiving arthroscopy or mini-open, and 6% in those receiving open dislocation
 - Neurological complications were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure.
 - Level of Evidence: Low due to lack of study quality
- ✓ KQ5: Differential Efficacy
 - No studies compared differential efficacy of treatment in subpopulations
 - Five studies looked at outcomes following surgery in two subpopulations: Osteoarthritis and Chondral damage
- ✓ KQ5: Summary:
 - No study evaluated the differential efficacy or safety of treatment for FAI
 - Outcomes following FAI surgery were consistently worse in patients with greater preoperative osteoarthritis compared with those with less osteoarthritis
 - There was no reported difference in outcomes in patients with varying degrees of chondral damage assessed during surgery
 - Level of Evidence: Very low due to lack of study quality, quantity and consistency of results
- ✓ KQ6: Cost Effectiveness –
 - We were unable to find any cost-effectiveness, cost utility or costing studies on this topic.
- ✓ Conclusion:
 - No data for efficacy of surgery or long-term effectiveness
 - Very low evidence on effectiveness of surgery in the short term
 - Conversion rate to THA depends on preoperative osteoarthritis status
 - Short term reoperation rate ranges from 4% to 9%
 - The idea of a low morbidity procedure that could prevent progression of DJD in young people with abnormal hip morphology is attractive; however, data are limited to support this hypothesis

Agenda Item: HTCC Femoroacetabular Impingement Syndrome (FAI) Discussion and Findings

C. Craig Blackmore, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost-effectiveness of FAI 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 stated that there are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in over-coverage of the femoral head). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration.
- 1.2 The evidence based technology assessment report indicated that surgery to correct FAI includes arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

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 reported that six comparative studies, 31 case-series and three case-reports were found that reported complications following surgical treatment for FAI in non- or recreational athletes. Altogether, 20 studies reported on arthroscopy, ten on open dislocation and seven on the mini-open procedure.
- 2.2 The evidence based technology assessment report indicated reoperation for reasons other than a conversion to a total hip arthroplasty occurred 3.8% in patients undergoing arthroscopy, 4.4% in those receiving open dislocation and 8.7% in patients following a mini-open procedure. There was only one reported head-neck fracture (<0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion. Heterotopic ossification occurred in 2% to 3% of those receiving arthroscopy or mini-open, and 6% in those receiving open dislocation.
- 2.3 The evidence based technology assessment report indicated neurological complications (nerve palsy, paresthesia, and neuropraxia) were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure. Most were transient in nature. Three case-reports described an occurrence of extravasation of fluid into the abdomen/chest during arthroscopic treatment of FAI. In one case, the fluid extravasation resulted in an intra-abdominal compartment syndrome that presented as cardiopulmonary arrest.

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 *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report indicated that no randomized controlled trials (RCTs)



comparing surgery with conservative care for FAI or comparing different surgical treatments for FAI was found.

- 3.2 *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report identified one study that retrospectively compared conservatively treated patients versus those receiving FAI surgery versus patients having a total hip arthroplasty in the short-term (<5 year follow-up). In addition, the report identified four comparative studies which investigated the effectiveness of various surgical treatments for FAI: labral debridement versus labral refixation (two studies) and osteoplasty versus no osteoplasty (two studies). The first study poorly describes the selection of patients so that it was not possible to tell how the treatment and control groups were obtained. The last four studies use historical controls. There was no evidence identified that one specific treatment resulted in better outcomes than another (surgery versus no surgery, labral debridement versus refixation, osteoplasty versus no osteoplasty).
- 3.3 *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report identified 27 case series that reported on clinical outcomes following treatment for FAI in non- or recreational athletes. All studies report improvement in pain, patient-reported and clinician-reported hip outcomes scores, patient satisfaction and return to normal activities following FAI surgery.
- 3.4 *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report stated that approximately 8% of patients diagnosed with FAI who undergo surgery in published series go on to have a total hip arthroplasty within 3 years. There are no long-term (≥ 10 years) data available to assess long-term effectiveness of FAI surgery. There are no data yet published to test the hypothesis that FAI surgery prevents or delays hip osteoarthritis or the need for total hip arthroplasty.
- 3.5 *Hip surgery for FAI compared with no surgery:* The evidence based technology assessment reported six comparative studies, 31 case-series and three case-reports were found that reported complications following surgical treatment for FAI in non- or recreational athletes. Altogether, 20 studies reported on arthroscopy, ten on open dislocation and seven on the mini-open procedure.

4. Special Populations

- 4.1 The evidence based technology assessment report indicated no studies were found comparing the differential effectiveness of surgery versus nonsurgical care in FAI patients. However, five studies were identified that looked at outcomes following surgical treatment for FAI in two subpopulations, those with varying degrees of osteoarthritis as assessed by the Tönnis grade and patients with varying degrees of chondral damage assessed during surgery.
- 4.2 The evidence based technology assessment report indicated that outcomes following FAI surgery were consistently worse in patients with greater preoperative osteoarthritis compared with those with less osteoarthritis. In one study, the relative risk of a conversion to total hip arthroplasty (THA) in those with preoperative Tönnis grade 2–3 was 58 (95% CI: 8, 424) compared with Tönnis grade 0-1. There was no reported difference in outcomes in patients with varying degrees of chondral damage assessed during surgery. No data from other subpopulations were found.

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 assessment report indicated no cost effectiveness, cost utility or costing studies were found on FAI surgery.

6. Evidence on Medicare Decision and Expert guidelines

Committee reviewed and discussed the Medicare Decision and expert guidelines as identified and reported in the technology assessment report.

- 6.1 The Centers for Medicare and Medicaid Services have no national or local coverage determinations or policies regarding the surgical treatment of FAI syndrome.
- 6.2 Guidelines – a search of the core sources and relevant specialty groups identified three guidelines.
 - National Institute for Health and Clinical Excellence (NICE), 2007: The National Institute for Health and Clinical Excellence (NICE), (which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales) concluded in 2007 that current evidence on the efficacy and safety of both arthroscopic surgery for the treatment of FAI syndrome “does not appear adequate for these procedures to be used without special arrangements for consent and for audit or research”; further publications of safety and efficacy outcomes will be needed. NICE stated that only surgeons with specialist expertise in arthroscopic hip surgery should perform this procedure for FAI and that the natural history of FAI syndrome and the selection of patients for this procedure are uncertain; further research on these issues will be useful.
 - National Institute for Health and Clinical Excellence (NICE), 2011: In July 2011, NICE published an updated report on arthroscopy for FAI syndrome in the form of a rapid review of the medical literature and specialist opinion. The review is based on approximately 1126 patients from three non-randomized controlled trials, five case-series, and one case-report. Several short-comings in the available literature were addressed such as overall poor study quality, limited prospective data collection in case-series, variability of outcome assessment scales used and lack of validation of these scales, heterogeneity in treatments making comparison between studies difficult, and descriptions of hip impingement pathology/lesions not well defined in all studies. The specialists’ concluded that “there is no proof yet that this procedure is efficacious, but the technique may have a place in preventing the development of osteoarthritis of the hip in some patients”. They also stated that use of this procedure will become more widespread, but should remain with the confines of the specialist dealing with hip disorders in young adults.
 - National Institute for Health and Clinical Excellence (NICE), 2011: NICE published an updated guidance report on open surgery for FAI in July 2011 stating that “current evidence on the efficacy of open femoroacetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term. With regard to safety, there are well recognized complications. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit with local review of outcomes.

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 FAI has been collected and summarized.

- 1.1 The committee agreed that FAI is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint are thought to cause friction/impingement and pain.
- 1.2 The committee agreed that there are two types of FAI: cam impingement and pincer impingement. Furthermore, the committee agreed that surgery to correct FAI includes arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that FAI is unproven to being equally safe to alternative treatments. Key factors to the committee's conclusion included:

- 2.1. The committee agreed that there is insufficient evidence about the safety of FAI.
- 2.2. The committee agreed that they were concern regarding the reoperation rates and neurological complications.

3. Is it effective?

The committee concludes that the comprehensive evidence indicates that FAI is unproven to being more effective than alternative treatments. Key factors to the committee's conclusion included:

- 3.1. The committee unanimously agreed that insufficient evidence exists regarding the theory that FAI prevents osteoarthritis.
 - The committee noted there are no prospective comparative data.
 - The data available tends to be small, non-controlled case-series.
- 3.2. The committee unanimously agreed that no data is available to assess the short- or long-term efficacy of FAI surgery compared with no surgery.
- 3.3. The committee agreed that no one specific treatment resulted in better outcomes than another (surgery vs. no surgery; labral debridement vs. refixation; osteoplasty vs. no osteoplasty).
- 3.4. The committee agreed that no data exists to assess long-term effectiveness of FAI surgery compared with no surgery.

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 there is inadequate evidence to identify characteristics that either enhance or reduce the efficacy of FAI. Yet, the committee agreed that the procedure is being relatively being performed on younger patients.
- 4.2. The committee agreed that no studies were available comparing the differential efficacy, effectiveness or safety of surgery versus nonsurgical care in FAI patients.

5. Is it cost-effective?

The committee concludes that no compelling evidence exists with respect to FAI being cost-effective.

5.1. The committee agreed that no evidence was reported to conclude that FAI is cost effective.

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 concluded that the current evidence on Femoroacetabular Impingement Syndrome (FAI) demonstrates that there is insufficient evidence to cover. 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. Based on these findings, the committee voted to not cover Femoroacetabular Impingement Syndrome (FAI).

Femoroacetabular Impingement Syndrome (FAI) 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.

Femoroacetabular Impingement Syndrome (FAI) Evidentiary Votes:

Is there sufficient evidence under some or all situations that Femoroacetabular Impingement Syndrome (FAI) are:

| | Unproven (no) | Equivalent (yes) | Less (yes) | More (yes) |
|-----------------------|--------------------------|-----------------------------|-----------------------|-----------------------|
| Effective | 10 | 1 | 0 | 0 |
| Safe | 8 | 0 | 3 | 0 |
| Cost-effective | 11 | 0 | 0 | 0 |

Femoroacetabular Impingement Syndrome (FAI) Vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

| HTCC COMMITTEE COVERAGE DETERMINATION VOTE | | | |
|--|--------------------|--------------------------------|---|
| | Not covered | Covered Unconditionally | Covered Under Certain Conditions |
| Femoroacetabular Impingement Syndrome (FAI) | 9 | 0 | 2 |

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Femoroacetabular Impingement Syndrome (FAI) reflective of the majority vote.

The committee reviewed the Clinical guidelines and Medicare decision. The Centers for Medicare and Medicaid Services have no published national coverage determinations (NCD) for any Femoroacetabular Impingement Syndrome (FAI). Therefore, the committee’s coverage determinations are consistent with the clinical guidelines.

Health Technology Clinical Committee**Findings and Coverage Decision****Topic:** Hip Surgery for Femoroacetabular Impingement Syndrome (FAI)**Meeting Date:** September 16th, 2011**Final Adoption:****Number and Coverage Topic**

20110916B – Hip Surgery for Femoroacetabular Impingement Syndrome (FAI)

HTCC Coverage DeterminationHip Surgery for Femoroacetabular Impingement Syndrome (FAI) is **not a covered benefit****HTCC Reimbursement Determination**

- ❖ **Limitations of Coverage**
 - N/A
- ❖ **Non-Covered Indicators**
 - Hip Surgery for Femoroacetabular Impingement Syndrome (FAI)
- ❖ **Agency Contact Information**

| Agency | Contact Phone Number |
|---|-----------------------------|
| Labor and Industries | 1-800-547-8367 |
| Public Employees Health Plan | 1-800-762-6004 |
| Health and Recovery Services Administration | 1-800-562-3022 |

Health Technology Background

The Hip Surgery for Femoroacetabular Impingement Syndrome (FAI) was selected and published in December 2010 to undergo an evidence review process. The evidence based technology assessment report indicates that Femoroacetabular impingement (FAI) syndrome is a recently recognized diagnosis in primarily younger individuals where relatively minor abnormalities in the joint (orientation or morphology) are thought to cause friction/impingement and pain. It is theorized that FAI starts the breakdown of cartilage, leading to osteoarthritis. There are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in over coverage of the femoral head). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration.

Hip surgery is an invasive procedure to correct FAI using either an open surgery or arthroscopic approach. The surgeon cuts off abnormal outgrowths of bone, removes damaged cartilage, and reshapes the femoral neck to ensure that there is sufficient clearance between the rim of the joint socket and the neck of the femur. After corrective surgery, avoidance of weight bearing for several weeks to months and rehabilitation is required. Surgery to correct FAI includes arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.

In July 2011, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Hip Surgery for Femoroacetabular Impingement Syndrome (FAI) report is 165 pages.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on September 16th, 2011, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The evidence based technology assessment report indicates:

- The evidence based technology assessment report stated that there are two types of FAI: cam impingement (non-spherical femoral head or abnormality at the head-neck junction) and pincer impingement (deep or retroverted acetabulum resulting in over-coverage of the femoral head). Proponents believe that surgical correction of the impinging deformities will alleviate the symptoms and retard the progression of OA degeneration.
- The evidence based technology assessment report indicated that surgery to correct FAI includes arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur.
- 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. Is the technology safe?

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.

- The evidence based technology assessment reported that six comparative studies, 31 case-series and three case-reports were found that reported complications following surgical treatment for FAI in non- or recreational athletes. Altogether, 20 studies reported on arthroscopy, ten on open dislocation and seven on the mini-open procedure.
- The evidence based technology assessment report indicated reoperation for reasons other than a conversion to a total hip arthroplasty occurred 3.8% in patients undergoing arthroscopy, 4.4% in those receiving open dislocation and 8.7% in patients following a mini-open procedure. There was only one reported head-neck fracture (<0.1%) and no reports of AVN, osteonecrosis or trochanteric nonunion. Heterotopic ossification occurred in 2% to 3% of those receiving arthroscopy or mini-open, and 6% in those receiving open dislocation.
- The evidence based technology assessment report indicated neurological complications (nerve palsy, paresthesia, and neuropraxia) were rare in those receiving arthroscopy or open dislocation; however, they occurred in 22% of 258 hips undergoing a mini-open procedure. Most were transient in nature. Three case-reports described an occurrence of extravasation of fluid into the abdomen/chest during arthroscopic treatment of FAI. In one case, the fluid extravasation resulted in an intra-abdominal compartment syndrome that presented as cardiopulmonary arrest.

3. Is the technology effective?

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.

- *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report indicated that no randomized controlled trials (RCTs) comparing

surgery with conservative care for FAI or comparing different surgical treatments for FAI was found.

- *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report identified one study that retrospectively compared conservatively treated patients versus those receiving FAI surgery versus patients having a total hip arthroplasty in the short-term (<5 year follow-up). In addition, the report identified four comparative studies which investigated the effectiveness of various surgical treatments for FAI: labral debridement versus labral refixation (two studies) and osteoplasty versus no osteoplasty (two studies). The first study poorly describes the selection of patients so that it was not possible to tell how the treatment and control groups were obtained. The last four studies use historical controls. There was no evidence identified that one specific treatment resulted in better outcomes than another (surgery versus no surgery, labral debridement versus refixation, osteoplasty versus no osteoplasty).
- *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report identified 27 case series that reported on clinical outcomes following treatment for FAI in non- or recreational athletes. All studies report improvement in pain, patient-reported and clinician-reported hip outcomes scores, patient satisfaction and return to normal activities following FAI surgery.
- *Hip surgery (open or arthroscopic) compared with no surgery for FAI:* The evidence based technology assessment report stated that approximately 8% of patients diagnosed with FAI who undergo surgery in published series go on to have a total hip arthroplasty within 3 years. There are no long-term (≥ 10 years) data available to assess long-term effectiveness of FAI surgery. There are no data yet published to test the hypothesis that FAI surgery prevents or delays hip osteoarthritis or the need for total hip arthroplasty.
- *Hip surgery for FAI compared with no surgery:* The evidence based technology assessment reported six comparative studies, 31 case-series and three case-reports were found that reported complications following surgical treatment for FAI in non- or recreational athletes. Altogether, 20 studies reported on arthroscopy, ten on open dislocation and seven on the mini-open procedure.

4. **Special Populations?**

- The evidence based technology assessment report indicated no studies were found comparing the differential effectiveness of surgery versus nonsurgical care in FAI patients. However, five studies were identified that looked at outcomes following surgical treatment for FAI in two subpopulations, those with varying degrees of osteoarthritis as assessed by the Tönnis grade and patients with varying degrees of chondral damage assessed during surgery.
- The evidence based technology assessment report indicated that outcomes following FAI surgery were consistently worse in patients with greater preoperative osteoarthritis compared with those with less osteoarthritis. In one study, the relative risk of a conversion to total hip arthroplasty (THA) in those with preoperative Tönnis grade 2–3 was 58 (95% CI: 8, 424) compared with Tönnis grade 0-1. There was no reported difference in outcomes in patients with varying degrees of chondral damage assessed during surgery. No data from other subpopulations were found.

5. **Is the technology cost-effective?**

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.

- The evidence based technology assessment report indicated no cost effectiveness, cost utility or costing studies were found on FAI surgery.

6. **Medicare Decision and Expert Treatment Guidelines**

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

- The Centers for Medicare and Medicaid Services have no national or local coverage determinations or policies regarding the surgical treatment of FAI syndrome.
- Guidelines – a search of the core sources and relevant specialty groups identified three guidelines.
 - National Institute for Health and Clinical Excellence (NICE), 2007: The National Institute for Health and Clinical Excellence (NICE), (which provides guidance on health technologies and clinical practice for the National Health Service in England and Wales) concluded in 2007 that current evidence on the efficacy and safety of both arthroscopic surgery for the treatment of FAI syndrome “does not appear adequate for these procedures to be used without special arrangements for consent and for audit or research”; further publications of safety and efficacy outcomes will be needed. NICE stated that only surgeons with specialist expertise in arthroscopic hip surgery should perform this procedure for FAI and that the natural history of FAI syndrome and the selection of patients for this procedure are uncertain; further research on these issues will be useful.
 - National Institute for Health and Clinical Excellence (NICE), 2011: In July 2011, NICE published an updated report on arthroscopy for FAI syndrome in the form of a rapid review of the medical literature and specialist opinion. The review is based on approximately 1126 patients from three non-randomized controlled trials, five case-series, and one case-report. Several short-comings in the available literature were addressed such as overall poor study quality, limited prospective data collection in case-series, variability of outcome assessment scales used and lack of validation of these scales, heterogeneity in treatments making comparison between studies difficult, and descriptions of hip impingement pathology/lesions not well defined in all studies. The specialists’ concluded that “there is no proof yet that this procedure is efficacious, but the technique may have a place in preventing the development of osteoarthritis of the hip in some patients”. They also stated that use of this procedure will become more widespread, but should remain within the confines of the specialist dealing with hip disorders in young adults.
 - National Institute for Health and Clinical Excellence (NICE), 2011: NICE published an updated guidance report on open surgery for FAI in July 2011 stating that “current evidence on the efficacy of open femoroacetabular surgery for hip impingement syndrome is adequate in terms of symptom relief in the short and medium term. With regard to safety, there are well recognized complications. Therefore this procedure may be used provided that normal arrangements are in place for clinical governance, consent and audit with local review of outcomes.

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 concluded that the current evidence on Femoroacetabular Impingement Syndrome (FAI) demonstrates that there is insufficient evidence to cover. 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. Based on these findings, the committee voted to not cover Femoroacetabular Impingement Syndrome (FAI).

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Femoroacetabular Impingement Syndrome (FAI)

Draft Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Femoroacetabular Impingement Syndrome (FAI).

| Commenter | Comment Period October 10 th – 24 th | Cited Evidence |
|--|---|----------------|
| Patient, relative, and citizen | 7 | 0 |
| Legislator and public official | 0 | 0 |
| Physician and health care professional | 2 | 0 |
| Industry and Manufacturer | 1 | 1 |
| Professional Society and Advocacy Organization | 0 | 0 |

All Total = 10

Comments with Evidence:

Industry and Manufacturer

Paul Just, PharmD, BCPS, Director, Healthcare Economics, Smith & Nephew, ASD

- Supports the treatment of FAI surgery, requests that the committee reconsider their coverage determination. Stated that conservative, non-surgical treatment of patients with symptomatic FAI is widely acknowledged in the medical literature to: not provide permanent symptom relief; require lifestyle modification; and, fail to allow patients to return to previous activity levels. The fact that cost-effective surgery for symptomatic FAI is covered in any other state in the nation and by most commercial insurers should cause concern to affected constituents whom, without access to this reparative surgery, are unlikely to find living with permanent hip pain and disability an acceptable level of health care. Furthermore, he stated that in 2010, an AMA review process found the evidence of safety and benefit for FAI surgery in symptomatic patients credible enough to grant three Category 1 CPT codes effective January 2011. Criteria for such codes include “that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature.” Lastly, he stated that the National Institute for Clinical Excellence (NICE), released guidance in September 2011 and July 2011, respectively, on arthroscopic and open surgery for FAI stating published evidence is adequate that surgery in symptomatic patients with FAI results in short- and medium-term benefits.

Comments without Evidence:

Physician and Health Care Professional

James D. Bruckner, MD, Board Certified Orthopaedic surgeon

- Dr. Bruckner does not support the HTCC's coverage determination on FAI surgery. He expressed his concerns on the following issues: disappointed that he was not offered the opportunity to participate in the development of the key questions, and that he was not asked to be a clinical reviewer for the HTA. Stated that he felt that the contracted review process is biased since he believes that the final key questions were modified from the key questions finalization to the development of the draft report. Stated that the preparers of the HTA systematically, and artificially excluded well done per reviewed literature that support the efficacy of surgical treatments of FAI. Supports the approach to treatment of FAI adopted by the vast majority of our regional health care providers. That is to develop specific criteria for the surgical treatment of these patients, based on the best current scientific evidence, and to track the results. This approach would be consistent with the current recommendations of NICE for surgical treatment of FAI. Lastly, he offered to assist in the development of surgical criteria and follow-up measures for the treatment of FAI.

Michael C. Sherfey, D.O.

- Supports the surgical treatment of FAI and requests that the committee reconsider their coverage determination. Stated that specific criteria for the surgical treatment of these patients should be based on current scientific and peer-reviewed evidence. Recommended that hip arthroscopy be indicated for FAI, labral pathology and loose bodies. The latter two of these could be documented by MRI. FAI may be documented by clinical exam findings combined with x-ray, and/or CT examination.

Patient, relative, and citizen

Danielle Cuevas

- Patient unhappy about the committee's coverage determination for FAI surgery. An MRI and diagnostic injection were administered. All non-invasive treatments failed to resolve Danielle's hip injury suffered from a work related incident. The diagnostic tools and treatments resulted in no improvement with pain or range of motion in the hip. Physician informed patient that all efforts and modalities were exhausted and surgical intervention was the best resort. Requests for the committee to reconsider their coverage determination on FAI surgery.

Julia Barklow

- Supports the surgical treatment of FAI and requests that the committee continue to cover FAI until some better qualifying questions are asked from patients post-surgery. Agrees that there should be specific criteria set for granting this procedure.

Leslie McGinnis

- Supports the surgical treatment of FAI and requests that the committee cover the treatment of FAI surgery.

Lindsey Daniels

- Supports the surgical treatment of FAI and requests that the committee cover the treatment of FAI surgery.

Cori Perez

- Wife of a LNI patient who has been diagnosed with FAI and a torn labrum, as well as a notch on the femur head from the length of time the patient went undiagnosed and untreated. Requests that the committee reconsider their coverage determination and that FAI surgery is allowed.

Carlos Perez

- LNI patient diagnosed with a hip contusion and lower lumbar strain. Doesn't agree with the committee's determination and requests that the committee reconsider the coverage determination made on FAI surgery.

Robert Riley

- Supports the surgical treatment of FAI and requests that the committee cover the treatment of FAI surgery.

TOPIC:

Femoroacetabular surgery for Hip Impingement (FAI)

Public meeting Date:

| | Actual Timeline | Total Public Comment Days |
|---------------------------------------|---------------------------------|----------------------------------|
| Preliminary recommendations published | <i>November 3, 2010</i> | |
| Public comments due: | <i>November 16, 2010</i> | 14 days |
| Selected set of topics published: | <i>December 17, 2010</i> | |
| Public comments due: | <i>January 17, 2011</i> | 32 days |
| Draft Key Questions Published: | <i>April 20, 2011</i> | |
| Public comments due: | <i>May 4, 2011</i> | 15 days |
| Key Questions Finalized: | <i>May 31, 2011</i> | |
| Draft report due: | <i>July 21, 2011</i> | |
| Draft report published: | <i>July 27, 2011</i> | |
| Public Comments due: | <i>August 17, 2011</i> | 22 days |
| Final report due: | <i>August 24, 2011</i> | |
| Final report published: | <i>August 26, 2011</i> | |
| Public meeting Date: | <i>November 18, 2011</i> | |
| Findings & Decision Published | <i>October 10, 2011</i> | |
| Public Comments due: | <i>October 24, 2011</i> | 15 days |

I Carlos Perez was injured October 12, 2007 at work, I was diagnosed with a hip contusion and lower lumbar strain. I went thru several treatments which were unsuccessful and have been misdiagnosed multiple times over the past few years with no relief or help from the treatment approved or suggested by LNI. This injury has affected my life as well as my families life financial, physically and mentally as we have not been able to enjoy our normal life style that we were accustomed to. I have finally been given the correct diagnoses and have surgery scheduled for this month, I am looking forward to gaining my life back and returning to the work force as this injury has prevented me from physically being able to return to the work force and enjoy life. I strongly believe that the LNI is responsible for covering the cost of the surgery and any treatment to follow as this injury is an issue that causes a lot of pain and physical problems that go undiagnosed and is something that will affect mine as well as others in the present or future if it goes untreated. This type of injury gives all the signs of back issues and is commonly misdiagnosed.

After seeing an Orthopedic Surgeon I was properly diagnosed as he listened to my problems and looked further into the hip and was able to successfully diagnose where the problem was generating from. I feel as though LNI will do everything possible to make you feel as though its all in your head and make the excuse of my age to prevent me from getting the proper treatment and benefit I deserve as I have worked consistently and have never been accused of malingering even by LNI's doctors this injury/condition does cause me to be prevented from working or enjoying life.

I have had several injections into the back, physical therapy, pain clinic treatment, chiropractic, massage therapy, plus many more different treatments and test that DID NOT give me any relief. I did however receive relief from the injection performed by the Orthopedic Surgeon which is what he expected due to the finding he provided me with. I have had pain in the back region, hip down to foot, cramps, muscle spasms, stabbing pains, depression, inability to enjoy time with family and friends limited activities all due to the hip injury which has been misdiagnosed for years.

Thank You,

Carlos D. Perez
P.O. Box 1732
Zillah, WA 98953
509-901-4718
carlosperez@charter.net

My husband was injured in October of 2007 while at work when he was pinned between 2 pieces of power equipment. He was taken to the hospital had x-rays done and was diagnosed with a hip contusion and lumbar strain.

Over the past 4 years he has suffered with extreme pain. This has limited his ability to do things he has enjoyed, from going on walks, hiking, dancing, carrying our children, sitting for long periods of time, standing for long periods of time, even having sex causes him to be in pain for days after. He used to enjoy mowing the yard, he took such pride in our yard. He can not sleep through the night because he is in so much pain. He tosses and turns trying to get comfortable. In addition to this he has been unable to work since early 2008 due to his level of pain.

He has complained to his doctors, physical therapists, psychologists, pain specialist, pain clinic, back surgeons about his back and hip pain. He has complained of feeling as if his hip was going to give out, his hip was popping, and had his hip give out on him. He has had severe back pain, including muscle spasms, sharp shooting pain from his thigh up to his shoulder blades. I have even seen him try and do laundry and be in so much pain that when I came around the corner he was on the floor on his hands and knees because he couldn't stand the pain.

My husband has received injections in the SI joint, and numerous injections in the lumbar region of his back, none of which gave him any relief. His doctors have given him a very large number of medications in order to try and help him with the pain. He has had a ton of physical therapy, massages and even attended a pain clinic to try and help him get better so he could return to work.

After his hip giving out at one point he was so ill that he was vomiting non-stop for over 5 days. The doctor had to give him an injection to stop his vomiting and some other meds. He had an MRI that showed a torn disc in his back. However, the doctors all said that this was not likely the cause of his pain. We were unable to see a back surgeon due to lack of approval through L&I. We had to pay out of our own pocket to see the surgeon, who indicated that surgery on the torn disc would not be beneficial at this point, as he did not believe that this was the source of the extreme pain that he was having.

We finally were referred to an orthopedic surgeon after our claim was close and we took matter into our own hands, who diagnosed an FAI at the first office visit, within about 5 minutes. We went back the next week for an MRI and he had numerous injections. This was the first time in 4 years that he had noticeable relief!! The problem was that the relief only lasted for a few weeks. The surgeon indicated that my husband has FAI and a torn labrum, as well as a notch on the femur head from the length of time he has undiagnosed and untreated. We are now scheduled for surgery this Friday.

My husband has been seen by numerous IME doctors who have said there is nothing wrong with him and that essentially he is faking and/or has chronic pain. He has seen psychiatrists who have indicated that he has severe depression and anxiety so much so that he is unable to work because of those conditions alone. He has been made to believe from years of no one being able to diagnose his condition as if it was all just in his head. My husband had basically lost hope that he would ever get better or be able to do the things he enjoys. This surgery is the only hope he has currently that he can get better.

When he entered the pain clinic he had been prescribed methadone to help him with the pain. Upon entry into the program he was taken off of methadone (which he had only been taking for approx. 3 weeks). As he gradually increased in activity in the program he was increasing in pain. He told the doctors this and they did not believe him. They ended up saying he was fully capable of returning to

work and that basically he needed more counseling to help him cope with chronic pain issues. His attending physician disagreed and could not see that he was in real pain and continued to attempt to diagnose the issue.

Our L&I claim was closed due to the majority of L&I's trusted doctors all saying that this was all in his head. He has not been able to return to work, his doctors still had not released him even though L&I closed the claim.

This entire ordeal has affected every aspect of our lives! My husband was always the main stable source of income. At the time of his injury he was working 4 jobs as I was on bed rest. Before this we had never paid a bill late, now we have been receiving foreclosure notices, had our power, water and phones shut-off.

We saw a vocational counselor appointed by L&I who indicated that it did not matter how limited my husband was in his functions, that he needed to suck it up and go back to work. She said that our family was large enough we could just get on welfare, which we eventually had to do.

We have a family of 6 and we are struggling. My husband can no longer mow the lawn, he can't take out the garbage, he can't push a shopping cart through the store, sometimes he can not even tolerate walking from one side of the store to the other. He can not carry dog food or water softener salt. He is always so down because he just can't do what he used to do.

It has been horrible watching him suffer, and even worse watching him grow more and more depressed and lose hope as to ever feeling better. I have developed serious depression and anxiety issues due to the amount of stress that is on me to handle everything with our kids, house, my business and his injury.

I am hoping that this surgery will give my husband some relief as the injections did. I can not handle watching him in so much pain and be so down on himself. He blames himself for everything our family has gone through, he says if I didn't get hurt none of these things would've happened.

My husband wants to go back to work, he wants to be able to take care of his family. He believes that after this surgery he will be able to finally get some relief and eventually return to work. He used to provide medical benefits for our family. Now we are just barely surviving on food-stamps and state medical.

So far we have gone through 4 years of hell because my husband is in pain, it has hurt our entire family. If he had been diagnosed sooner, I do not believe he would be as bad as he is now. He has complained that he is getting worse as this 4 year period has drug on. The doctors have noted that he has been getting progressively worse as time has gone on. It is not a condition that should be ignored. This condition causes serious issues and serious pain!

I can only hope that you reconsider your decision as to no longer allow FAI surgery. This is a condition that drastically changes peoples lives and should not be ignored. My husband has done everything his doctors have ever suggested he do to help him feel better. He has jumped through all of the hoops L&I has set up and given that L&I listens to your opinions and acts based on your findings I believe that you need to think about the people your decision affects as well as the families. It is not ok for people to suffer the way my husband has, due to lack of a diagnoses. It would be even worse for people to not

have the option of getting a resolution to their condition and to be forced to suffer because they can not get the surgery they need to repair the damage caused by this condition.

Sincerely,
Cori Perez
Concerned wife of injured worker w/ FAI & labral tear

Thanks,

Cori Perez
Broker/Owner
YV Wine Country Properties
PO Box 1732
Zillah, WA 98953
509 901-3636 cell
509 314-6183 fax
coriperez@charter.net

To Whom It May Concern,

October 24, 2011

I am writing this letter in regard to the recent denial of authorization from Labor and Industries for Femoral Acetabular Impingement surgery that Dr. Bruckner deemed necessary to correct the recent damage sustained during a work related injury on 02/05/2011.

Back in May of 2008 I suffered a work related injury. While working in the back of a paramedic unit with a patient, we were struck by another driver at highway speeds. The diagnosis at the time was back and hip injuries. The MRI revealed that a right hip labral repair was necessary at that time. Dr. Bruckner performed this surgery to correct the tear. Although the recovery was lengthy, when I recovered, I felt that I was able to do the activities, live my life and do the job I as well as I did prior to the injury. I passed the physical agility test required to be a paramedic prior to returning to work without difficulty. I felt that Dr. Bruckner's efforts were so effective, that I confidently returned to work when released and closed my claim without any hesitation.

Regarding the current injury I sustained on 02/05/2011, while working as a paramedic, I was picking up a patient on the gurney and I felt my hip pop. Instantly I had pain, and was treated immediately by the urgent care physician delegated by my company. I was instructed to follow-up with Dr. Bruckner. In doing so, he advised let it heal on its own. In time, that didn't prove to be effective, so then other diagnostic procedures were warranted to determine the level of damage I sustained. An MRI and diagnostic injection were administered. All non-invasive treatment failed to resolve my hip injury. The diagnostic tools and treatments resulted in no improvement with pain or range of motion in my hip. Dr. Bruckner concluded that our efforts and modalities were exhausted and surgical intervention was the last resort.

From a personal standpoint, my life has been all but put on hold by this injury and I am not able to live the quality of life I had pre and post the last surgery. My daily pain level is at a chronic 4-6 on the pain scale. My strength has decreased; my physical disabilities have been substantially limited from the day of incident. I used to be able to run 5 miles 3 times per week. I was an active weight lifter to maintain the strength needed to be a firefighter. Most weeks I was in the gym 6 times per week. In addition to this, I was able to ski, mountain bike and participate in the activities that I love. All of this has had to stop.

I once took a great amount of pride in my physical fitness and strength, now it's a source of embarrassment even though I have no control over it due to my hip injury. I hate the thought of being physically disabled for the rest of my life, and this surgery is my only hope I have to return to full physical function again. I long for nothing more than to heal, get better, and move on with my life.

Please take this letter into consideration when you are making your final decision.

Sincerely,

Danielle Cuevas , Claim # AP546525

Leah Hole-Curry, JD

Program Director, Washington State Health Care Authority Health Technology Assessment Program

PO Box 42712

Olympia, WA 98504-2712

Dear Ms. Hole-Curry,

I appreciate the opportunity to comment on the Washington State Health Care Authority Health Technology Assessment (HTA) of Hip Surgery procedures for treatment of Femoroacetabular Impingement (FAI). In preparation, I have reviewed the entire HTA, and the peer review, public and Washington state agency comments and responses for FAI.

As background, I am a Board Certified Washington State licensed orthopaedic surgeon who has been performing hip arthroscopy since 1997. I did my first surgical dislocation for FAI in 1997, and developed my own arthroscopic technique for managing the condition in the same year. Since then, I have done nearly 2500 hip arthroscopy procedures, the majority of which involved FAI. I have partnered with a certified surgical coding specialist, and the medical insurance industry, to develop criteria for the management of FAI, and ultimately, CPT codes.

In the past 14 years, I have cared for countless patients for the State of Washington, and I have had success in returning these patients to gainful employment.

As the most experienced hip arthroscopist in the state, I am surprised that I was not offered the opportunity to participate in the development of key questions for the HTA. Nor was I asked to be a clinical reviewer for the HTA. As an academic orthopaedic surgeon with 10 years of experience running the joint replacement and hip preservation service at the University of Washington, I feel that I am qualified to comment on the HTA.

My first comment is perhaps the most germane, and speaks to the bias of this contracted review processes. If the contracted entity knows that answer the contractor is seeking, it will change the question to arrive at that answer. It was pointed out repeatedly in the comments made by Smith and Nephew, and ignored in the responses, that the final key questions changed dramatically from the beginning of the HTA, to the development of the draft. Take as an example question 3. In the original charter: "What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) for FAI?" In the draft: "What is the evidence of efficacy and effectiveness of hip surgery (open or arthroscopic) compared with no surgery for FAI?" This profound change was perpetuated in key questions 4,5, and 6.

In reviewing the detailed Smith and Nephew comments on the draft report, it is apparent that the preparers of the HTA have systematically, and artificially excluded well done peer reviewed

literature that supports the efficacy of surgical treatment of FAI. Nevertheless, the bulk of the literature still reports good outcomes, and low complication rates for surgical treatment of this condition.

I suspect that this was plainly obvious to the researchers performing this literature review. The only way around the obvious conclusion that arthroscopic surgery is effective and safe for the treatment of FAI, is to change the question, and conclude that it has not been proven to be effective and safe in comparison to no treatment, while conveniently ignoring the fact that in these surgical trials, each patient serves as their own control, having failed appropriate no surgery treatment.

This error alone is egregious, and dooms this report. But there is more. In their policy context, the HTA states that “proponents (of FAI treatment) believe that surgical correction for the impinging deformities will ... retard the progression of OA degeneration. They go on to imply that there is a lack of prospective randomized clinical trials that prove that surgical treatment of FAI prevents the development of hip arthritis. If the HTA establishes a measure of scientific proof that cannot be achieved for a developing surgical procedure, then it will get the answer it wants. I will restate the point made by Smith and Nephew on page 17 of public comments...given the documented failure of conservative treatment for this condition, it is ethically impossible to establish a prospective trial to answer the modified HTA question of the effectiveness and safety of this procedure compared to no treatment.

Furthermore, as an experienced hip replacement surgeon and hip arthroscopist, I know that virtually all of my male patients undergoing hip replacement under the age of 60 have FAI, and second only to acetabular dysplasia, FAI is the etiology of hip arthritis in my female patients under the age of 60. Yet I will not make the assertion that early treatment of this condition will prevent the development of osteoarthritis, even though I know it will reliably relieve symptoms and restore normal activity. Proof that surgical treatment of FAI prevents the development of osteoarthritis of the hip is a red herring. That study cannot be ethically done, and the preparers of the HTA know this.

As an analogy, consider the reconstruction of the torn anterior cruciate ligament of the knee. We know that the unreconstructed anterior cruciate deficient knee is doomed to develop arthritis. We also know that the reconstructed knee is more stable, and less symptomatic, but unfortunately, after decades of clinical followup, is still more prone to develop early arthritis. If we were to apply this HTA methodology to reconstruction of the torn ACL, we would likely conclude that “significant questions remain about the ... efficacy and effectiveness” of the procedure.

At 165 pages, this HCA is thorough, but unfortunately fatally flawed. If, as an associate professor at the University of Washington, I had conducted a research project based on a null hypothesis, and then changed that hypothesis after collecting my data, I would have rightly been excused from the faculty.

If the flawed conclusions of this HTA are accepted by the Washington State Health Care Authority, patients with symptomatic FAI who are covered by the state will not stop having

symptoms, but they will be arbitrarily assigned to the no treatment group. The state will then be responsible for the management of their hip osteoarthritis, whenever it occurs. It may be more prudent for the State to embrace the approach to treatment of FAI adopted by the vast majority of our regional health care providers. That is to develop specific criteria for the surgical treatment of these patients, based on the best current scientific evidence, and to track the results. This approach would be consistent with the current recommendations of NICE, in the UK, for surgical treatment of FAI, and I consider NICE to be the most conservative of health technology assessment organizations.

I would be happy to assist in the development of surgical criteria and follow-up measures for the treatment of FAI for the State of Washington.

Sincerely,

James D. Bruckner, MD

FAX Transmission

Number of pages including cover sheet 3

Attention: Jessica Lentz & Lori Stearns Date: 10/24/2011

Company: Polliance Orthopaedics From: Leslie McGinnis

Phone: 425 507 0770 Company: _____

Fax: (425) 462 0830 Phone: 360 969 4470

Comments: Feel free to make corrections on spelling, technical names, etc.

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10/24/2011

To who it may concern.

I am writing to you today to explain why my hip arthroscopy surgery is necessary.

While working 4/16/2011, I stood up and I banged my hip hard on the corner of my clients sink. After 40 minutes I was in excruciating pain. I went to the local emergency room and was diagnosed with a bone contusion. The pain did not heal as predicted.

Finally after 4 months a contrasting MRI was done and it was discovered a lapreion tear had occurred when I hit my hip.

My pain gets worse daily. I am in danger of losing my job as I can only do extremely light duty work and my clients are getting frustrated with that. On the personal side, I have not been able to have sex with my fiancée since 4/16/2011. (We have tried 3 times and have been unable to complete the act).

HT 40000

I am in danger of losing him because of this.

I no longer am able to do things I do for enjoyment such as dance (including slow dancing), walking, swimming, workout on my exercise equipment and so much more. Sleeping is difficult as I have to change position often due to pain. I can no longer sit or stand for long periods of time, I have to change position every 15 minutes or so.

All of this is making me depressed which I already have issues with.

Before my injury, I had gotten my weight down to 149 and my health was improving. Since the injury I am up to 183 and my health is declining.

Please help me. I am only 41 yrs old. Approve my surgery so I can have my life back.

Respectfully



An excerpt from:

Health Technology Clinical Committee

Findings and Coverage Decision

Topic: Hip Surgery for Femoroacetabular Impingement Syndrome (FAI)

Meeting Date: September 16th, 2011:

"Hip surgery is an invasive procedure to correct FAI using either an open surgery or arthroscopic approach. The surgeon cuts off abnormal outgrowths of bone, removes damaged cartilage, and reshapes the femoral neck to ensure that there is sufficient clearance between the rim of the joint socket and the neck of the femur. After corrective surgery, avoidance of weight bearing for several weeks to months and rehabilitation is required. Surgery to correct FAI includes arthroscopy, open dislocation of the hip and arthroscopy combined with a mini-open approach. The purpose of the surgery is to remove abnormal outgrowths of bone and damaged cartilage, and to reshape the femoral neck to ensure that there is sufficient clearance between the rim of the acetabulum and the neck of the femur."

The arthroscopic FAI procedure is not invasive... are we comparing total hip replacement to FAI?

I am a recent recipient (10/10/2011) of surgery involving Femoroacetabular Impingement Syndrome (FAI). I live on a remote island in Alaska. I travelled to Washington state for relief of an injury I sustained while on active duty in the military. In a nutshell, I was being carried (bride-style) by a fireman who was evacuating me from an IED-simulated explosion. He subsequently threw me flat on my back on the ground, from about four feet, as he stumbled and fell while he was running with me in his arms. For over a year, I was treated for my back pain. Fortunately, I had one persistent physical therapist who suggested an MRI w/contrast to check my hip. I had had four epidurals in my L-4 region to try to get me relief of my chronic pain, but nothing was touching the pain, except for the numbing agent prior to the procedure. Then, once again, I gained relief from the numbing agent for introducing the contrast for the MRI.

My first appointment was with an orthopaedic specialist in Anchorage, Alaska. He suggested a full hip replacement. He was set in his determination to use a posterior entry, thereby cutting the muscle from the bone, inserting the metal replacements, and then re-attaching the muscle back to the bone. One precaution to that procedure would find me never bending from the waist. I was not comfortable with that precaution. I sought a second opinion whereby the surgeon spoke about hip preservation. He would repair the Labral tear found in the MRI, and resurface the irregularities in my femoral head. I understood that the irregularities potentially contributed to my Labral tear because of the position my hip was in when I was thrown to the ground - the irregularity might have 'caught' the Labrum and tore it. Makes perfect sense to me... I was all about prevention of this nightmare to happen again!!

The report I read on the HTA website (above) mentions FAI surgery to be invasive, but in the same sentence says arthroscopic. I have two small incisions for the insertion of the arthroscopes used in my FAI. Invasive?

Also, the above report suggests "avoidance of weight bearing for several weeks to months and rehabilitation required."

I am not sure who is suggesting no weight bearing, but my surgeon told me to weight bear as I was getting dressed to leave the hospital. I had crutches, but they were merely to 'slow me down' as my surgeon suggested. Which also makes me wonder if the subjects in the research were asked if they honestly followed their surgeons directions?

Once home, I believe the body needs time to rest and recover. I took my pain medications on schedule, and basically slept, watched TV, read, and ate in bed for a week. I used a cold therapy device on the manufacturer's recommended on/off schedule and maneuvered around my home on my crutches during that week as well.

Now, into my second week of recovery today, 10/24/2011, I am a new woman!! I have ZERO back pain, normal recovery pain in my hip, but nothing like what I endured for over a year! The pain now is different - very slight... I don't need pain medication for it. Eventually, at my six-week mark, I will begin to follow what my doctor suggested as my physical therapy: Two steps forward, and one step back. Basically, it means I can exercise towards a goal, (in variables), be it time, resistance (stationary bike, elliptical, etc.), elevation or pace. I am to take steps to get there by advancing in the variable, but scaling back if there is pain.

I have a completely renewed outlook on life. I cannot imagine denying patients with my similar situation this FAI procedure. I went through the suggestions that the pain was in my head, but this deep pain is very real, diagnosed (thank heavens for

MRIs), and relieved by the repair of my Labral tear and FAI to prevent it from happening again. Basically, I 'fit' better than I did. The body is a remarkable thing, but some portions need tweaking.

I agree there should be specific criteria set for granting this procedure, but I suggest the HTA pursue that cause and refrain from telling patients FAI is a 'not covered' benefit until some better-qualifying questions are asked from patients post-surgery. FAI is an advancement in hip preservation; I cannot understand the idea to deny people in constant pain at least the choice and screening for the procedure.

Thank you for providing this forum for our voices to be heard.

Respectfully,
Julia Barklow
Kodiak, Alaska
(907) 486-1701

To Whom It May Concern,

I hope you will read this in its entirety, as I am someone who has had a hip arthroscopy and FAI surgery on my left hip and am expecting to have it on my right hip in December. I have lost almost a year of my life and I am hoping that you can give me the five minutes I deserve, to read about my story.

I was laid off from designing at a software company in January because of injuries resulting from a car accident, and even though I did the right thing by following my primary doctor's direction, physical therapy didn't help but only put more pain to the problem of the tear and FAI. I feel my primary doctor didn't listen to me and kept brushing me off and was negligence in my delay of treatment. After several months of traditional conservative therapy, surgery has been my only hope.

I was a passenger of a car accident on December 4, 2010. My mother was driving and we were traveling at about thirty-five miles per hour on Bothell-Everett Highway when a car to my right pulled out to cross the highway in front of us. I was taken to the hospital and had x-rays and CT scans which came back clear. My primary doctor then told me to do physical therapy but the pain kept progressing from my hips, lower back, all the way up to my neck. I had an MRI of my cervical and thoracic spine, which came back clear as well. The pain kept radiating from my hips to lower back, so I had an MRI of my lower lumbar, which came back clear. It makes sense now though because although the upper body pain was mostly soft tissue damage, the hips are the foundation and the lower back pain was coming from the muscles attached to the hips. I soon realized that something was extremely wrong with my body as it radiated to my groin, SI joint, and the side and back of my hip and pelvis. I was told to do physical therapy.

I tried traditional land-based physical therapy and it was so painful that the therapist transferred me to their physical therapy aquatic program, walking the length of the pool because I was too frail to continue therapy on land. My first two toes would go numb and tingle and I had intense pain around my pelvis and hip, and down my SI joint as well as my groin. I told my primary doctor that my physical therapist suggested I get an MRI to check and see if I had a torn labrum and my doctor shrugged it off and told me to do yoga. I could hardly walk, so there was no way I could do yoga. I continued to do pool-based physical therapy as he also suggested.

I tried cranial sacrum therapy for two months. I tried medical massage therapy and chiropractic adjustments for eight months. I had a cortisone injection. I had been taking naproxen and ibuprofen for eight months. I consistently applied an ice and heat contrast. I tried soaking in a hot tub for six months. I tried bio-freeze. I have been seeing a counselor every few weeks for eight months, due to all the stress and depression that the pain from the car accident has caused me. Working in the pool with a physical therapist for six months, I was exhausted and could hardly walk because it was becoming too painful, even though I was only walking the length of the pool and doing twenty-five lunges in the pool.

The pain became more and more intense and my primary doctor finally ordered an MRI for me. First he only ordered a regular MRI, which then the radiologist canceled and had to order a contrast MRI to show the tear. If there is already a problem in the area, any extra fluid is extremely painful and I found this out the hard way. After the contrast injection, I was still crying three hours afterward, and was taken to the walk-in clinic and given an anti-inflammatory shot. The doctor who saw me and ordered the anti-inflammatory shot actually saw the results of the MRI and told me I had a tear. The following week, I saw my regular doctor and he then told me my MRI was "normal" even after the walk-in clinic doctor told me otherwise. He misdiagnosed me and I was tired of being told nothing was wrong, especially after the walk-in clinic doctor just told me there was a visible tear. I then asked to see a specialist because I was

tired of my primary doctor telling me nothing was wrong statistically to match what I was saying and the pain I was experiencing.

I was sent to a DO who saw the cleft on the MRI and sent me to my surgeon, Dr. James Bruckner. Along with the tear I also have FAI and the surgery was scheduled for late August. For the first time, after trying conservative therapy for almost nine months, I started to feel hope. He also took me off physical therapy and I was put on crutches in June because it got to the point that I couldn't walk anymore. The pain was terrible, horrendous.

By June my family had to move my bed downstairs because I couldn't walk up the stairs without pain. I could not sleep on my stomach or either side anymore. I had to use a lighter blanket instead of my comforter at night because the weight of the blanket causes pain if I move my legs. I was on crutches for five months up until two weeks ago because I had to live on crutches for almost three months prior to having my hip arthroscopy and FAI surgery, and almost for one and a half months after surgery.

My right hip is hurting from compensating. I recently got an MRI on it and found out it's torn too. If my primary doctor had listened to me from the beginning and not misdiagnosed me, I could have had my MRI on my left hip and had everything detected and had surgery much sooner. Instead, I had to deal with this for almost nine months and now my opposite hip has to have surgery because it is torn from compensating all my body weight from being on crutches. They both burn and ache all the time. I could not stand for more than a few minutes with the crutches because any weight on my hips was unbearable. I had to sit at a 120 degree angle because it was so painful. I had to stop driving and have my mom drive me to my appointments because it causes pain. I had to lean back when sitting in the car and still have to do that. I have pain when I twist, rotate, and can hardly bring my knees up. It was so painful and sometimes takes someone to help me get up and out of a chair. The action of sitting down on a chair was also very difficult and painful.

I have tendonitis in my hip flexors and am still recovering from surgery on my left hip. My surgeon said there was much more cartilage damage than he had expected. From the ten o'clock to two o'clock angle, my labrum was removed and he shaved down my impingement. He said he was able to save a good amount of cartilage. As I am still recovering from my first surgery and am waiting to have my surgery on the opposite hip in December, I still cannot stand and cook and make meals any longer. I can't go hiking or kayaking like I used to. I can't go to the beach with crutches. I can't go grocery or recreational shopping because I can't carry anything. I can't lift weights or maintain my arm strength because I cannot bear any weight. I cannot maintain my endurance and my cardio health because I can't ride a bicycle, jump, skip, walk, jog, run, sprint, etc. I can't maintain my flexibility because I can't stretch. I can't sit on my knees. I can't bend down to pick up things like laundry, or dishes in and out of the bottom rack of the dishwasher because it is extremely painful. I can't take out the garbage for garbage pick-up. I can't garden and harvest vegetables. I can't go on family vacations. I can't have a normal social life with friends who don't understand and gave up on me. I can't dance, and have been dancing for sixteen years. Before my surgery, both legs felt like they are hanging by threads from my hips and my hips feel like they were constantly having multiple migraines. I have become so depressed and worried about my future to bear children safely and to be able to walk and live without pain.

I've had to quit back-up singing in a professional band, lost income through that source and lost professional relationships. I was also laid off from my job, as stated before, because I cannot walk and get to work because of the pain, which caused me to lose my income. I am still unemployed. I missed my uncle's funeral because riding in a car a third of the way to his service, my hip pain flared up, the pain intensified, and I had to call my mother to get me and take me home. Aside from the physical burning

pain, feeling like I am not living because I am not able to live with the pain is emotionally really depressing. I don't know what I would do if I couldn't have this surgery.

After having the first surgery, my pain level went down tremendously and I have been able to walk again without crutches. The left side, the side that was operated on, feels like it is slowly getting better. I am going to start physical therapy soon, but I am starting to slowly walk up the stairs. My right side is getting worse and worse from it being torn and now walking on it again is very painful. I have to get my left side that was just operated on strong enough to use crutches and bear all of my right side's weight after I have surgery on my right side on December 2, 2011.

My car accident was December 4, 2010. I've lost almost a year out of my life, my career, income, and only gained significant pain and depression. My condition resulted from a driver making a bad decision and pulling out in front of the car I was riding in. If this condition happened because of work and if I was told by L&I or insurance company that my surgery was not covered, I would feel totally hopeless for my future. I can't imagine not being able to have this surgery or ever walk again. I can't imagine being in pain and suffering my entire life. I wouldn't want to keep living if all I felt was pain. I'm only twenty-six years old.

You must know that I am a young adult who volunteered four years of her life without pay, to help orphanages and at-risk-youth, and then came home to WA and worked at a software company for one year as their In-House Designer, meanwhile while attending school full-time for Web Design and Development. My goal was to bring this skill set to the nonprofit I helped start (The [Film Art Institute](#)) and add a web curriculum for at-risk youth. Imagine being an ambitious person like me, who wants to help the world, and having to stay at home because of the pain, unable to walk, drive, work, or be with family and friends, and unable to volunteer, and feeling like I am not giving hope to these children who don't have the educational encouragement that I have had, growing up with my mother as a teacher. I am so fortunate that my mother has been able to provide food and shelter for me or I would have had no help through all this, as I was laid off due to this accident.

Now, imagine ambitious people like Dr. James Bruckner, who want to save the world in his way too, and is being held back from helping people heal because the Healthcare Technology Assesment's decision to no longer pay for FAI surgery. Please do not keep other people from having this surgery. It's not fair to take away the only option they have to living a pain-free life. Because of this surgery, I have been able to walk again! This surgery works and there is a reason people fly into WA to Dr. Bruckner, because it works. My heart is sad for the people who cannot have this surgery, whose insurance is denying them. Some people can't work because of the pain, and can't make money to live and don't have a family member to help them, like I do. This is the only option. If you take it away, you're taking away their right to life, liberty, and happiness.

Sincerely,

Lindsey Daniels

Leah Hole-Curry, JD

Program Director, Washington State Health Care Authority Health Technology
Assessment Program

PO Box 42712

Olympia, WA 98504-2712

Dear Ms. Hole-Curry,

I would like to take this opportunity to comment on the Washington State Health Care Authority Health Technology Assessment (HTA) of Hip Surgery procedures for treatment of Femoroacetabular Impingement (FAI).

My training includes subspecialty fellowship in hip replacement and hip preservation treatment options. I am one of the few hip subspecialists in the southeastern region of Washington State performing hip arthroscopy. I have been performing hip arthroscopy for patients since 2009. Most of my patients' symptoms are involved with underlying femoroacetabular impingement (FAI) and labral pathology. In my opinion, many of these patients benefit from symptomatic relief of hip pain along with improvement in activity and function. I also feel that this procedure works well as a less-invasive alternative for loose body removal of the hip. Long-term alteration in the development of significant hip arthritis is less clear. For this reason I routinely do not consider hip arthroscopy as a treatment option for those with known significant hip arthritis. The indications for hip arthroscopy continue to be defined, and the technology and technical advances now allow for a less invasive option compared to arthrotomy and surgical hip dislocation.

Specific criteria for the surgical treatment of these patients should be based on current scientific and peer-reviewed evidence.

I think the HTA involvement in hip arthroscopy is actually a good initiative, and could lead to the development of meaningful guidelines for the state of Washington. I regret coming to table at such a late date; yet would be happy to participate in developing guidelines, should the deadline for comment be extended. In the absence of that, I would recommend hip arthroscopy be indicated for FAI, labral pathology and loose bodies. The latter two of these could be documented by MRI. FAI may be documented by clinical exam findings combined with x-ray, and/or CT examination.

Sincerely,

Michael C. Sherfey, D.O.

Paul M. Just, PharmD, BCPS
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Josh Morse
Program Director, Washington State Health Care Authority
Health Technology Assessment Program
P.O. Box 42712
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VIA E-MAIL

October 24, 2011

Dear Mr. Morse:

Smith & Nephew, Inc. is a global medical technology business specializing in Orthopaedics (Trauma and Total Joint Reconstruction), Endoscopy and Advanced Wound Management. Smith & Nephew is a global leader in the development and manufacture of devices used in arthroscopic surgery.

We appreciate that the Washington State Health Care Authority Health Technology Assessment Program accepts comments on the Findings and Coverage Decision report released October 11 for the topic Hip Surgery for Femoroacetabular Impingement Syndrome (FAI).

Conservative, non-surgical treatment of patients with symptomatic FAI is widely acknowledged in the medical literature to: not provide permanent symptom relief; require lifestyle modification; and, fail to allow patients to return to previous activity levels.(1-19) The fact that cost-effective surgery (20) for symptomatic FAI is covered in any other state in the nation and by most commercial insurers should concern your affected constituents whom, without access to this reparative surgery, are unlikely to find living with permanent hip pain and disability an acceptable level of health care.

According to strict evidence-based criteria for evaluating the quality of any given medical or surgical publication, the quality of few individual study reports is considered high. If such a standard was applied to the majority of medical and surgical literature, few rational effective treatments would be available and patient health would suffer. Bad patient care ultimately leads to increased medical resource consumption.

In patients with symptoms and a documented inability to participate in desired daily activities once considered routine, health technology appraisals conducted by all but one national U.S. commercial insurer found the collective evidence credible that FAI repair surgery for these patients is safe and effective. Millions of covered lives across the United States are covered for corrective surgery for symptomatic FAI under specified conditions, often including the failure of non-surgical conservative management to relieve pain and allow patients to return to their previous activity level.

In 2010, an AMA review process found the evidence of safety and benefit for FAI surgery in symptomatic patients credible enough to grant three Category 1 CPT codes effective January 2011. Criteria for such codes include “that the clinical efficacy of the service/procedure is well established and documented in U.S. peer review literature.”

The National Institute for Clinical Excellence (NICE), a global leader in evidence-based health technology appraisals, released guidances in September 2011 and July 2011, respectively, on arthroscopic and open surgery for FAI stating published evidence is adequate that surgery in symptomatic patients

with FAI results in short- and medium-term benefits. Previous guidance for either surgery stated that evidence was not sufficient for this conclusion but patient access to the surgery was not blocked.

Section 6 of the Findings and Coverage Decision memorandum from the WSHCA still does not report this finding correctly. Additionally, the 2007 guidance from NICE, based primarily on pre-2007 data, is irrelevant today because of 416 total publications on FAI in the literature as of September 2, 2011, 359 (86%) were published in 2007 or later.

Since 2008, six independent evidence-based systematic reviews of surgery for FAI in symptomatic patients concluded that the published evidence supports its safety and effectiveness.(21-26) Additional favorable reports have subsequently been published. There are no unfavorable reports.

The published evidence of clinical outcomes from surgery for patients with symptomatic FAI includes over 40 peer-reviewed publications by various surgeons using arthroscopic, open or a combination of these surgeries reporting that patients' symptoms are relieved and that the majority of patients are capable of returning to their previous desired level of activity.(1-3;5-11;13;14;17-19;27-54) Arthroscopic surgery for FAI was associated with the lowest overall risk of complications.

Among these peer-reviewed publications, 19 reports with over 1000 patients indicated that surgery was only performed in symptomatic FAI patients that had failed non-surgical conservative management comprised of medication, reduced activity and physical therapy or rehabilitation programs lasting up to over one-year. In these patients, 75 percent to 100 percent were reported able to return to their previous state of joint health allowing them to return to meaningful recreational and work activities within months.(1-5;7-14;17-19;43;51;53).

A just published cost-effectiveness analysis of FAI surgery compared to observation of patients with symptomatic FAI, with an endpoint of delaying total hip replacement surgery, found FAI surgery to be very cost-effective according to the definition of cost-effectiveness used by the World Health Organization.(20) Using the best evidence available in the literature, the authors developed a credible cost-effectiveness model demonstrating that the cost-effectiveness of FAI surgery compared to observation was \$21700 per quality adjusted life year (QALY) for patients with no radiographic evidence of arthritis. A cost per QALY below the gross domestic product (GDP) per capita of a given country is considered very cost-effective. A cost per QALY below three times the GDP per capita is considered cost-effective and, at \$79,500/QALY for patients identified to have preoperative arthritis, FAI surgery would be considered cost-effective even in this subset of patients.(20) However, conventional FAI surgery is not recommended in patients found to have advanced arthritis during the pre-operative assessments.

Your recommendation will prevent patients with symptomatic FAI, who are suffering from chronic pain and lifestyle altering disability, from having access to surgeries found to have adequate evidentiary support for their reasonableness, safety, effectiveness and medical necessity by a near unanimous preponderance of medical authorities outside the state of Washington. We urge you to do what is in the best interest of your patients and reconsider the no coverage recommendation.

Yours Truly,

Paul M. Just, PharmD, BCPS
Director, Healthcare Economics

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Hi,

I am writing to you because I received a call from my orthopedic surgeon's office today. They told me that the Department of Labor and Industries is considering NOT covering the surgery that I am scheduled for (Hip Arthroscopy).

I have an open claim with L&I regarding a work related injury to my hip. I was injured in August of this year. I am still waiting for the determination of my claim with L&I; therefore I have not heard anything from L&I regarding the determination of potential treatments (i.e.: surgery).

After my injury, I was diagnosed and scheduled for surgery in December... I have been anxiously waiting for this surgery. Since the injury I have experienced severe pain that effects my day to day activities and sleep. I have not been able to perform my usual work duties and am currently not working, due to lack of light duty work available with my employer. Then today I received a call letting me know that similar patients with my problem, are being denied by L&I for this procedure. I was told that L&I does not find the surgery to be medically necessary.... How is that possible, if my surgeon says that it is necessary and I know from experience that the symptoms do not go away on their own, even with no aggravation from work?

As I understand it, if I do not get the surgery, there is no way to improve my hip pain and if I let it go as is, I will eventually need total hip replacement surgery. If I do not get the surgery I will no longer be able to work in my current occupation, therefore would need re-training. Also, even if I change professions, if I attempt to continue living a healthy, active lifestyle my hip will continue to give me a lot of pain and discomfort, inhibiting my daily activities and then eventually leading to total hip replacement surgery (which would completely fix my problem, allowing me to return to my previous occupation and make the re-training process a waste of time and money). I am not open to the concept of pain management either... I do not like the idea of being dependent on pain medication for the rest of my life, especially when my orthopedic surgeon tells me there is a surgery that will fix my problem long term.

I feel so strongly about this, that if L&I moves forward with the decision to deny my surgery option, I will find a way to pay for the surgery myself. I have been living with this debilitating pain for months now, waiting for my scheduled surgery, only to find out that it may not be approved. What is wrong with the system, that this surgery can be all-inclusively denied instead of evaluated on a case by case basis? If this surgery is truly

unnecessary as L&I is saying, then what is the "better" option? Or are they simply putting the expense of the surgery over patient's needs?

Feel free to contact me with questions, responses or if you would like further comment.

Regards,

Robert Riley
425-508-8664

Health Technology Clinical Committee

Findings and Coverage Decision

Topic: Positron Emission Tomography (PET) Scans for Lymphoma

Meeting Date: September 16th, 2011

Final Adoption:

Number and Coverage Topic

20110916A – Positron Emission Tomography (PET) Scans for Lymphoma

HTCC Coverage Determination

Positron Emission Tomography (PET) scans for Lymphoma is a **covered benefit with conditions**

HTCC Reimbursement Determination

❖ **Limitations of Coverage**

- Positron Emission Tomography (PET) scans for Lymphoma is a covered benefit when the following conditions are met:
 - One scan for initial treatment planning;
 - Additional scans for restaging with clinical suspicion of disease progression or treatment failure subject to agency approval;
 - No coverage for routine surveillance

❖ **Non-Covered Indicators**

- N/A

❖ **Agency Contact Information**

| Agency | Contact Phone Number |
|---|-----------------------------|
| Labor and Industries | 1-800-547-8367 |
| Public Employees Health Plan | 1-800-762-6004 |
| Health and Recovery Services Administration | 1-800-562-3022 |

Health Technology Background

The Positron Emission Tomography (PET) for Lymphoma was selected and published in December 2010 to undergo an evidence review process. The evidence based technology assessment report indicates that an estimated 74,000 US individuals will be diagnosed with lymphoma [about 65,500 non-Hodgkin lymphoma (NHL) and 8,500 Hodgkin lymphoma (HL)]. This makes NHL approximately eight times more frequent than HL.

Lymphoma is divided into Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL) based on the histological pattern of the malignancy. Hodgkin lymphoma is an uncommon malignancy involving lymph nodes and the lymphatic system. Two age ranges predominate — 15 to 30 years and over 55 years. Two types of Hodgkin lymphoma are identified — classic (CHL) (95%) and nodular lymphocyte-predominant (LPHL) (5%). Classic HL is further divided into four types — nodular sclerosis, mixed cellularity, lymphocyte depleted and lymphocyte rich. Non-Hodgkin lymphomas (NHL) are a heterogeneous group of lymphoproliferative malignancies originating in B-lymphocytes (80-85%), T-lymphocytes (15-20%) and natural killer lymphocytes (<1%). NHLs are separated into indolent, aggressive and highly aggressive categories based on their natural history. However, natural history of these lymphomas tends to correlate with histological cell type.

Positron emission tomography (PET) is a nuclear medicine diagnostic test that uses a positron emitting radioactive particle, currently fluorine-18 (¹⁸F) as a radioactive tracer. For imaging of known or suspected cancer, ¹⁸F is incorporated into a glucose molecule (¹⁸FDG) and injected into the blood stream. ¹⁸FDG preferentially accumulates in areas of high glucose metabolism including many cancer cells. Thus, areas of cancer are identified as areas of high radioactivity or “hot spots” on the scan image. The “hot spot” images from PET scanning have low spatial resolution so it may be difficult to determine the exact location of abnormal areas from the PET scan alone. As a result, in 2011 PET is usually performed on a combined PET-CT scanner where both the radioactive PET data and high spatial resolution CT data are recorded at the same time. This results in more precise localization of areas of abnormal glucose metabolism in the body. The claim for PET compared to other imaging methods such as MRI and CT is that uptake of ¹⁸FDG by cancer cells is both more sensitive and specific for cancer than alterations in local anatomy and tissue properties that might be detected by MRI and CT. However, false negative PET scans can result from areas of cancer that may be too small or too metabolically inactive to accumulate enough ¹⁸FDG to be detected by the PET scan. Alternatively, false positive PET scans can result from other causes of increased glucose metabolism such as hyperemia, infection, inflammation or tissue healing that may lead to abnormal accumulation of ¹⁸FDG and then appear as “hot spots” on PET scans.

In July 2011, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Positron Emission Tomography (PET) for Lymphoma report is 80 pages.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on September 16th, 2011, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The evidence based technology assessment report indicates:

- Positron emission tomography (PET) is a diagnostic imaging test using a positron emitting radioactive particle. In PET for cancer, the radioactive particle is currently ¹⁸fluorine (¹⁸F) which is incorporated into a glucose molecule ¹⁸FDG. When injected into the blood stream, ¹⁸FDG preferentially accumulates in areas of high glucose metabolism such as areas of active cancer. The PET scan produces areas of increased radioactivity (referred to as “hot spots”) where cancer cells are metabolically active. Positron emission tomography is frequently performed after other imaging methods, such as CT or MRI, so it may not replace other imaging tests. In current practice, PET is normally performed on a fusion PET/CT scanner which produces PET “hot spot” data and CT anatomic data synchronously. The claim for PET is that the changes in glucose metabolism detected by PET are more sensitive and specific for presence of viable cancer than CT or MRI, which rely on changes in local anatomy and tissue properties.
- Lymphoma is a heterogeneous group of lympho-proliferative malignancies involving lymph nodes, bone marrow, spleen and other extra-lymphatic organs that affects approximately 74,000 individuals in the US annually. Lymphoma is divided into Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). In turn, NHL is divided into many sub-types that are usually grouped into aggressive NHL (aNHL) and indolent NHL (iNHL).
- It is estimated that 74,000 US individuals will be diagnosed with lymphoma [about 65,500 non-Hodgkin lymphoma (NHL) and 8,500 Hodgkin lymphoma (HL)]. This makes NHL approximately eight times more frequent than HL. Depending on type and stage of lymphoma, five year survival rates are as high as 80 to 90%. Accurate information about diagnosis and staging is important for planning the most appropriate treatment strategy, response to treatment, and monitoring for recurrence. Histopathologic tissue examination is necessary for definitive diagnosis of HL or NHL. A patient’s physical symptoms, palpation, biopsy, magnetic resonance imaging (MRI), computed tomography (CT), gallium, and positron emission tomography (PET and PET/CT) can be used to assess patients. Positron emission tomography and PET/CT (collectively PET) are increasingly performed to inform staging, restaging, and estimation of prognosis after treatment and surveillance for recurrence of cancer.
- Evidence included in the technology assessment review was obtained through a structured, systematic search of the medical literature; economic studies; and clinical guidelines. MEDLINE search retrieved 354 full citations from which 18 observational studies were included. Core source searched yielded 7 SRs and TAs, 3 cost or cost-effectiveness study designs and 6 clinical practice guidelines.
- The evidence based technology assessment report identified six expert treatment guidelines. CMS Decision Memo (2010): CMS did NOT issue a national coverage decision. CMS (2010) has a new PET framework:
 - Initial treatment strategy: NCD of one PET
 - Subsequent anti-tumor treatment strategy: left to local regional carriers to decide
 - Exception for lymphoma – cover all PET

- 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. Is the technology safe?

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.

- The evidence based technology assessment report indicates that there is limited evidence on safety. Although, there is moderate radiation dose associated with each PET and PET/CT scan performed, lymphoma is a potentially lethal disease. Concern for the effects of radiation may be more important for younger patients and for repeated PET and CT studies during follow-up. The overall strength of evidence is low.
- The evidence based technology assessment report indicated that the Australia MSAC (2010) addressed the question of safety of PET. No evidence directly addressed safety of PET in lymphoma. Australia MSAC believed that data on safety for PET for other indications can be reasonably applied to PET for lymphoma. Australia MSAC concludes that PET for lymphoma is safe.
- The evidence based technology assessment report indicated that potential safety issues for PET would include contrast reactions, radiation dose levels and incidental findings. The radiopharmaceutical ^{18}F FDG used for PET scanning is an analog of glucose. Intuitively, ^{18}F FDG should be well tolerated as a glucose analog, and no contrast reactions have been noted for ^{18}F FDG. Radiation dose from PET (and PET/CT) is significant. Radiation dose from PET is 10-30 mSv (approximately 300 chest x-ray equivalents). Dose from CT varies depending on whether the CT is a low-dose CT performed to anatomical correlation only or a standard CT. Dosage from standard CT is also 10-30 mSv (also equivalent to approximately 300 chest x-rays). Dosages from PET/CT must be added.

3. Is the technology effective?

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.

- Screening and Diagnosis – the evidence based technology assessment report indicated that there is no evidence about the use of PET for either screening of asymptomatic patients or in making a diagnosis of lymphoma. The diagnosis of lymphoma always requires tissue sampling (biopsy) for histological diagnosis.
- Original Staging by PET (or PET/CT) Compared with Conventional Staging or as an Incremental Test to Conventional Staging –
 - *Hodgkin and Aggressive Non-Hodgkin Lymphoma (aNHL)*: the evidence based technology assessment report indicated that staging for HL and aNHL is normally performed after diagnosis and before primary treatment in order to determine the extent of disease. Staging is important because the detection of additional sites of HL or aNHL may alter both the stage and the planned treatment. The evidence based technology assessment reported that the Australian MSAC technology assessment *Positron Emission Tomography for Lymphoma* (2010) summarized four systematic reviews (Kwee, 2008; Facey, 2007; Pakos, 2005; Kirby, 2007) that address the use of PET for original staging. These systematic reviews evaluate PET compared to CT and/or to gallium scintigraphy. The Australian MSAC technology assessment also reviews two studies that evaluate PET as an incremental study to conventional staging. When

- compared to CT or gallium, PET appears to consistently have higher sensitivity and specificity than CT or gallium for staging of HL and aNHL. The sensitivity for PET in detecting HL and aNHL at initial staging ranges from 88-100% compared to sensitivity for CT of 88% and for gallium of 20-93%. Specificity for PET ranges from 90-100% compared to 80% for the specificity of CT. The evidence based technology assessment reported indicated that no RCTs or other study designs were identified for original staging.
- *Indolent Non-Hodgkin Lymphoma (iNHL)*: The evidence for PET staging is mixed. Positron emission tomography appears to detect additional disease compared to CT in a significant number of patients but also appears to miss disease detected by CT. The series by Fueger (2009) compared PET/CT to PET alone and CT alone and found that PET/CT performs better than either of the comparators. This is not surprising given the evidence from other series that PET and CT both detect disease missed by the other modality. The studies reported here did not clearly state the reference standard. This makes evaluation of the true sensitivity and specificity impossible. The quality of the case series is low and the overall strength of the evidence is low. The evidence for PET staging is mixed. Positron emission tomography appears to detect additional disease compared to CT in a significant number of patients but also appears to miss disease detected by CT. The series by Fueger (2009) compared PET/CT to PET alone and CT alone and found that PET/CT performs better than either of the comparators. This is not surprising given the evidence from other series that PET and CT both detect disease missed by the other modality. The studies reported here did not clearly state the reference standard. This makes evaluation of the true sensitivity and specificity impossible. The quality of the case series is low and the overall strength of the evidence is low. No RCTs were identified. Four case series report on accuracy of PET in original staging of iNHL. Fueger (2009) reported on 45 patients with iNHL who had PET/CT for original staging. Scott (2009) reported on 74 consecutive patients with iNHL who received PET after conventional staging; all 74 patients received PET and 16 patients also had gallium scans. Le Dortz (2010) retrospectively reviewed 45 patients with iNHL who underwent initial staging with CT and PET. Bodet-Milin (2010) retrospectively reviewed 45 patients with mantle cell lymphoma (iNHL) who underwent PET in addition to conventional scanning prior to treatment.
 - Routine Staging after Primary Treatment – the evidence based technology assessment report indicated one scenario for staging after primary treatment is the “routine” evaluation of every patient to evaluate for persistent or non-responsive lymphoma. The evidence for diagnostic accuracy of PET for staging is mixed. Some of the evidence evaluates PET as a substitute for conventional staging and some as an incremental study added to conventional staging. The underlying studies mix HL and aNHL populations for which, on at least one study, PET has different accuracy. The studies often mix initial staging with staging after primary treatment. Positron emission tomography appears to have higher sensitivity and specificity than conventional staging for detection of sites of lymphoma. Positron emission tomography certainly identifies more sites than conventional imaging; this phenomenon is typical for “hot spot” imaging techniques which produce information for the entire body instead of just the areas chosen for imaging (e.g., CT of the chest, abdomen and pelvis). Additional sites identified by PET will include true positive and false positive results. PET appears to perform better for original staging than for staging after primary therapy.
 - The evidence based technology assessment report indicated that no RCTs were identified. One small, single center case series reported on PET for staging after primary treatment (Cerci, 2010).



- Evaluation of Residual Mass after Primary Treatment – the evidence based technology assessment report indicated no RCTs or other study designs were identified of residual mass after treatment. PET appears to have heterogeneous results in the evaluation of residual mass after completion of primary therapy. Both sensitivity and specificity have wide ranges of 40-100%. Facey (2007) concluded that PET has higher specificity than CT but similar sensitivity. In the evaluation of a residual mass, both sensitivity and specificity have a comparable bearing on further clinical management and sensitivities or specificities of 40% may not yield reliable information for changing treatment decisions. The three systematic reviews are all rated fair to good. The underlying studies are case reports and were noted by systematic review authors to have methodological flaws. Given the heterogeneous results, the strength of the evidence is low.
- Estimation of Prognosis after Primary Treatment – the evidence based technology assessment report indicated no RCTs or other study designs were identified. One systematic review based on two case series evaluates the ability of PET at the end of primary treatment to predict subsequent outcome. Positron emission tomography appears to have a reasonable sensitivity but heterogeneous specificity in two studies. It appears to outperform CT in predicting subsequent outcome. The evidence is based on two small case series and overall strength is considered low.
 - The evidence based technology assessment indicated that Australia MSAC (2010) reported two case series of 99 and 127 patients that evaluated the ability of PET to distinguish between “responders” and “non-responders”. These two case series compared PET results with 2-3 year progression-free survival (PFS).
- Estimation of Prognosis after Secondary Treatment – the evidence based technology assessment report No RCTs were identified. Three case series address the ability of PET to predict relapse or recurrence after salvage treatment (Moskowitz, 2010; Doder, 2010 and Qiao, 2011). The statistics provided in the two systematic reviews and three case series make comparison difficult. It appears that PET has a lower sensitivity and specificity in predicting subsequent outcome after secondary treatment than after primary treatment. Likelihood ratios or hazard ratios of 3-4 and PPV and NPV of around 80% do not provide strong indication of subsequent outcome. As with estimation of prognosis after primary treatment, it is unclear if sensitivity, specificity and likelihood ratios values given here would alter subsequent management. Although the systematic review and case series are of moderate to good quality, the overall strength of the evidence is low.
 - The evidence based technology assessment report indicated two systematic reviews address the ability of PET to predict relapse or recurrence after salvage (secondary) treatment (Terasawa, 2010; Poulou, 2010).
- Surveillance of Asymptomatic Patients after Treatment – the evidence based technology assessment report indicated no systematic reviews or technology assessments that address PET in surveillance of patients without symptoms who are in remission after treatment for HL or aNHL. No RCTs were identified either. Five case series evaluate the value of PET during surveillance of patients with HL and aNHL in remission (Goldschmidt, 2011; Lee, 2010; Crocchiolo, 2009; Mocikova, 2010; and Petrausch, 2010). The evidence based technology assessment report indicated that the evidence for the use of PET for routine surveillance of patients in remission is consistent. Positron emission tomography performed on asymptomatic patients has a significant false positive rate. Clinical findings and original stage of HL or aNHL are good predictors of subsequent relapse or recurrence. Positron emission tomography does not appear to have a strong role in surveillance of asymptomatic patients. The evidence consists of five recent case series of poor to fair quality. The overall strength of the evidence is low.

- Monitoring of Response to Treatment during Treatment – the evidence based technology assessment report indicated that one systematic review and three case series investigated the ability of PET scan performed mid-cycle during primary treatment to predict subsequent outcome. Pooled sensitivity from Terasawa’s meta-analysis was 81% for HL and 78% for aNHL; specificity was 97% for HL and 87% for aNHL. Results from the three case series are comparable. Results for PPV and NPV from the case series vary from study to study (one study evaluated HL and another aNHL). It is uncertain if the diagnostic efficacy results are strong enough to justify management changes in mid-treatment. The results are internally consistent and overall strength of evidence is considered moderate.
 - The evidence based technology assessment report indicated a systematic review by Terasawa (2009) which evaluated the ability of PET to predict disease progression or relapse when performed in mid-cycle of primary treatment for HL or aNHL.
- Estimation of Prognosis during or after Treatment – *Indolent Non-Hodgkin Lymphoma (iNHL)*: the evidence based technology assessment report indicated that the evidence is limited to two small case series which suggest that PET findings are reasonably accurate in predicting early relapse of iNHL; a negative PET scan appears to be more valuable than a positive PET. The evidence is considered weak because of the small number of patients included in these case series, and the overall strength of evidence is low. No RCTs were identified.
- *Hodgkin and Aggressive Non-Hodgkin Lymphoma (aNHL)*: The evidence based technology assessment reported indicated no evidence was identified for the effect of PET on the reduction of other tests, patient survival or quality of life. There is limited evidence on changes in management. There is limited evidence on the effect of PET on patient management, quality of life or survival. The overall strength of evidence is considered low. *Indolent Non-Hodgkin Lymphoma (iNHL)*: Positron emission tomography appears to have modest impact on clinical decision making. The evidence is based on one small case series and is considered of low strength. No RCTs were identified. Scott (2009) reported on change in management after PET staging in a case series of 74 patients with iNHL.

4. **Special Populations?**

- The evidence based technology assessment report indicated that no evidence on special populations was reported.

5. **Is the technology cost-effective?**

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.

- The evidence based technology assessment report indicated that the evidence for costs of PET in lymphoma comes primarily from outside the United States. Several of the studies are valued in US dollars, but the medical delivery and payment systems are different than in the US. The evidence should therefore be interpreted with care. The cost data comes primarily from outside the US. The four studies identified use different cost assumptions. The savings from PET are small under any of the cost assumptions studied. The single US study found that routine surveillance imaging cost \$100,000 and had an increased radiation dose of 147 mSv per recurrence detected. The overall strength of evidence is low.
- Australia MSAC (2010) identified no published studies that it considers relevant or of sufficient quality to include. The authors performed an economic analysis based on using PET in place of conventional methods for staging. Assuming PET is used, the Australia MSAC estimates a savings of Australian \$150 (8%) per HL patient and Australian \$210 for NHL.

- The evidence based technology assessment report identified no RCTs.

6. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the expert guidelines as identified and reported in the technology assessment report.

- Centers for Medicare and Medicaid Services (CMS) – no NCD policy addressing children.
 - The evidence based technology assessment report indicated that in 2010, CMS issued a decision not to make a national coverage decision (NCD) for PET scanning in malignancies. This leaves ultimate coverage decisions on ¹⁸F¹⁸FDG PET to local Medicare carriers. In the Decision Memo, CMS (2010) created a two-part framework for analysis of PET use in malignancies—initial treatment strategy and subsequent anti-tumor strategy.
 - For Initial Treatment Strategy, CMS will “nationally” cover lymphoma and other solid malignancies for one FDG PET study for determining the optimal location to perform an invasive biopsy and to determine stage of the tumor. Moreover, CMS allows local Medicare contractors to make local decisions for coverage of additional PET scans for therapeutic purposes related to initial treatment strategy.
 - For Subsequent Anti-tumor Treatment Strategy, lymphoma is considered separately from other malignancies. Positron emission tomography is covered “nationally” without exception.
- Guidelines – the evidence based technology assessment report identified a total of nine guidelines in the core source search, and no additional guidelines were identified in the MEDLINE search. Of the original nine guidelines, four were excluded because they did not address PET scanning. The remaining guidelines include one from the *International Harmonization Project in Lymphoma (IHPL)* and two each from the *National Comprehensive Cancer Network (NCCN)* and the *American College of Radiology (ACR)*. The guidelines from NCCN and ACR were rated as fair quality and the guideline from IHPL was rated as poor quality. Poor quality ratings are primarily the result of undisclosed literature search methods for cited literature and for potential conflicts of interest of authors.
 - The evidence based technology assessment report indicated that the NCCN (2011a; 2011b) guidelines recommend the use of PET for initial staging of HL and aNHL. The NCCN recommends PET for staging in iNHL as optional but potentially useful in iNHL that appears to be localized and if concern exists about histological transformation. The NCCN guidelines recommend PET for evaluation of residual mass after treatment. The NCCN and IHPL (Juweid, 2007) guidelines recommend use of PET after treatment to determine prognosis. The IHPL guideline states that PET should only be performed in mid-cycle of treatment *if the findings will alter management*. The ACR (2010, 2011) guidelines caution that *changes in treatment based on PET findings should only be performed as part of a clinical trial*. Guidelines from NCCN and ACR recommend against the use of PET for routine surveillance. The ACR guidelines add that PET may be helpful in surveillance patients with clinical findings suspicious for relapse.
 - The evidence based technology assessment report indicated that the guidelines recommend the use of PET for initial staging of HL and aNHL. The routine use of PET to predict subsequent outcome is not recommended by the guidelines. Guidelines recommend against PET in surveillance of asymptomatic patients in remission after primary or secondary treatment. Guidelines are congruent with the evidence gathered for this report.

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 concluded that the current evidence on Positron Emission Tomography (PET) scans for Lymphoma demonstrates that there is sufficient evidence to cover with conditions PET scans for Lymphoma. 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. Based on these findings, the committee voted to cover with conditions Positron Emission Tomography (PET) scans for Lymphoma.

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC) determines how selected health technologies are covered by several state agencies (RCW 70.14.080-140). These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

Positron Emission Tomography (PET) Scans for Lymphoma

Draft Findings & Decision Timeline and Overview of Comments

The Health Technology Assessment (HTA) program received comments in response to the posted Health Technology Clinical Committee (HTCC) draft findings and decision on Positron Emission Tomography (PET) scans for Lymphoma.

| Commenter | Comment Period October 10 th – 24 th | Cited Evidence |
|--|---|----------------|
| Patient, relative, and citizen | 0 | 0 |
| Legislator and public official | 0 | 0 |
| Physician and health care professional | 0 | 0 |
| Industry and Manufacturer | 0 | 0 |
| Professional Society and Advocacy Organization | 1 | 0 |

All Total = 1

Comments without Evidence:

Professional Society and Advocacy Organization

Dave Fisher, Executive Director, Medical Imaging & Technology Alliance (MITA)

- Requests that the committee make the following modifications from the draft developed in the September 16th meeting, in order to align Washington State plan reimbursement policy with Medicare reimbursement policy: during the Initial Treatment Planning phase, allow reimbursement for PET scans performed subsequent the single initial staging scan, subject to agency approval; During the Subsequent Treatment Planning phase, explicitly provide for reimbursement for PET scans for recurrence and monitoring of therapy; and during the Subsequent Treatment Planning phase, eliminate the condition of reimbursement of restaging PET scans on agency approval.

TOPIC:

Positron Emission Tomography (PET) scans for Lymphoma

Public meeting Date:

| | Actual Timeline | Total Public Comment Days |
|---------------------------------------|---------------------------------|----------------------------------|
| Preliminary recommendations published | <i>November 3, 2010</i> | |
| Public comments due: | <i>November 16, 2010</i> | 14 days |
| Selected set of topics published: | <i>December 17, 2010</i> | |
| Public comments due: | <i>January 17, 2011</i> | 32 days |
| Draft Key Questions Published: | <i>May 11, 2011</i> | |
| Public comments due: | <i>May 25, 2011</i> | 15 days |
| Key Questions Finalized: | <i>June 3, 2011</i> | |
| Draft report due: | <i>July 21, 2011</i> | |
| Draft report published: | <i>July 28, 2011</i> | |
| Public Comments due: | <i>August 26, 2011</i> | 30 days |
| Final report due: | <i>August 31, 2011</i> | |
| Final report published: | <i>September 2, 2011</i> | |
| Public meeting Date: | <i>September 16, 2011</i> | |
| Findings & Decision Published | <i>October 10, 2011</i> | |
| Public Comments due: | <i>October 24, 2011</i> | 15 days |



MITA

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October 24, 2011

Leah Hole-Curry, JD
Program Director
Health Technology Assessment (HTA) Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Re: Draft Findings and Coverage Decision on the Use of Positron Emission Tomography (PET) Scans for Lymphoma, Submitted for Comment on October 10, 2011

Dear Ms. Hole-Curry:

The Medical Imaging and Technology Alliance (MITA) appreciates this opportunity to comment on the draft findings and coverage decision related to the use of PET scans for lymphoma as determined by the Washington State Health Technology Clinical Committee on September 16, 2011. As the leading trade association representing PET tracer developers, manufacturers, compounders and distributors, we have an in-depth understanding of the significant health benefits that PET technology provides patients diagnosed with lymphoma. MITA looks forward to working with you to continue exploring the effectiveness of this technology as the Clinical Committee finalizes its decision.

PET and PET with computed tomography (PET/CT) imaging have become invaluable tools in the detection, staging, and therapy management of patients with cancer and heart disease. PET/CT scans are highly accurate tests that deliver precise results demonstrated to routinely and significantly affect how physicians manage and treat their patients' disease. Most cancers are approved by CMS for coverage, including lymphoma, which is reimbursed for both initial and subsequent treatment strategies.

Our comments address the following aspects of the draft findings and coverage decision. First, we compare the draft coverage decision with the current Medicare National Coverage Determination (NCD) for PET for lymphoma. Second, we express our concerns with the initial coverage decision's restriction of patient access to PET scans for lymphoma beyond the limitations for Medicare patients in the areas of initial and subsequent treatment strategy. Third, we conclude with important modifications we urge the Clinical Committee to make before finalizing a coverage decision in this area.

I. Comparing the Clinical Committee’s Draft Coverage Decision to the Medicare National Coverage Determination for PET for Lymphoma

According to MITA’s interpretation, the draft coverage decision developed by HTA is substantially different from Medicare’s National Coverage Determination (NCD) in three key areas.

- 1. Additional Scans in Initial Treatment Planning** – Medicare’s NCD provides reimbursement for one PET scan for initial staging. Additional PET scans may be reimbursed, subject to carrier approval. In contrast, under the Clinical Committee’s draft decision, State health plans would provide reimbursement for a single PET scan for initial staging and would refuse payment for any additional PET scans, even if those scans are necessary.
- 2. Therapy Monitoring in Subsequent Treatment Planning** – Medicare’s NCD provides reimbursement for PET scans performed for restaging, recurrence, and monitoring of therapy. In contrast, the Clinical Committee’s draft decision would provide reimbursement from State health plans for restaging only. Although the draft decision does not directly address coverage of recurrence or monitoring of therapy, limiting reimbursement to restaging only would seemingly refuse payment for any PET scans for those purposes.
- 3. Additional Barriers in Subsequent Treatment Planning** – Medicare’s NCD provides reimbursement for PET scans for restaging, without restrictions. In contrast, under the Clinical Committee’s draft decision, State health plans would provide reimbursement only in cases in which the doctor received State agency approval.

II. MITA’s Concerns with Draft HTA Coverage Decision Restricting Access to PET Scans for Lymphoma

MITA is very concerned that the Clinical Committee is considering limiting access to PET scans for lymphoma patients beyond the limitations established by the Centers for Medicare and Medicaid Services for Medicare beneficiaries. Washington citizens insured through State health plans should have access to the same quality cancer care guaranteed to their neighbor or spouse who is covered by Medicare.

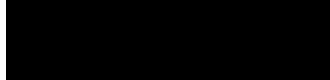
III. Recommended Modifications

In the final coverage decision, MITA urges the Clinical Committee to make the following modifications from the draft developed in the September 16 meeting, in order to align Washington State plan reimbursement policy with Medicare reimbursement policy:

- During the Initial Treatment Planning phase, allow reimbursement for PET scans performed subsequent the single initial staging scan, subject to agency approval.
- During the Subsequent Treatment Planning phase, explicitly provide for reimbursement for PET scans for recurrence and monitoring of therapy; and
- During the Subsequent Treatment Planning phase, eliminate the conditioning of reimbursement of restaging PET scans on agency approval.

MITA appreciates this opportunity to comment on the draft findings and coverage decision. We would be pleased to answer any questions you might have about these comments. Please contact me at (703) 841-3279 if MITA can be of any assistance.

Respectfully submitted,



Dave Fisher
Executive Director, MITA
Vice President, NEMA



Washington State
Health Care Authority

Health Technology Assessment Clinical Committee Meeting Program Update

Josh Morse, MPH
Health Technology Assessment
November 18, 2011

Presentation Overview

- HTA Program Overview
- HTA Program Updates
 - Topics

Today's Topics

- Microprocessor-controlled Lower Limb Prostheses
- Osteochondral Allograft / Autograft Transplantation (OAT)

Governor Gregoire's strategy : Improve quality in health care

- **Governor Gregoire's five point plan to improve health care (2005)**
 - *Emphasize evidence based health care*
 - Create more transparency in the health care system
 - Promote prevention, healthy lifestyles, and healthy choices
 - Better managed chronic care
 - Make better use of information technology
- **WA State Legislature and Blue Ribbon Commission (2006)**
 - Goals set for 2012 including use of evidence based medicine
- **Collaboration of Programs across State purchasing –**
 - Total of about 450,000 beneficiaries and 3.5 billion purchased
 - Health Care Authority – Public Employees and subsidized low income (Basic Health, Uniform Medical Plan, PEBB)
 - Medicaid Purchasing Agency – federal/state low income health care program with **fee for service** and managed care plans
 - Labor and Industries – **Worker's compensation** program
 - Department of Corrections – Correctional health care

2

Why Health Technology Assessment?

- **Part of an overall strategy**
- **Medical technology is a primary driver of cost**
 - The development and diffusion of medical technology are primary factors in explaining the persistent difference between health spending and overall economic growth.
 - Some health experts arguing that new medical technology may account for about one-half or more of real long-term spending growth.
Kaiser Family Foundation, March 2007: How Changes in Medical Technology Affect Health Care Costs
 - *Since technological change is the biggest contributor, an effective long-term strategy for controlling health care spending will probably have to address the health care system's way of incorporating new technologies into practice.*
U.S. Congressional Budget Office, *Technological Change and the Growth in Health Care Spending*, 2008. Report available at www.cbo.gov.
- **Medical Technology has quality gaps**
 - Medical technology diffusing without evidence of improving quality Highly correlated with misuses, overutilization, underutilization.

Cathy Schoen, Karen Davis, Sabrina K.H. How, and Stephen C. Schoenbaum, "U.S. Health System Performance: A National Scorecard," *Health Affairs*, Web Exclusive (September 20, 2006): w459 3

KEY HTA Products

Pay for What Works: Better Information is Better health

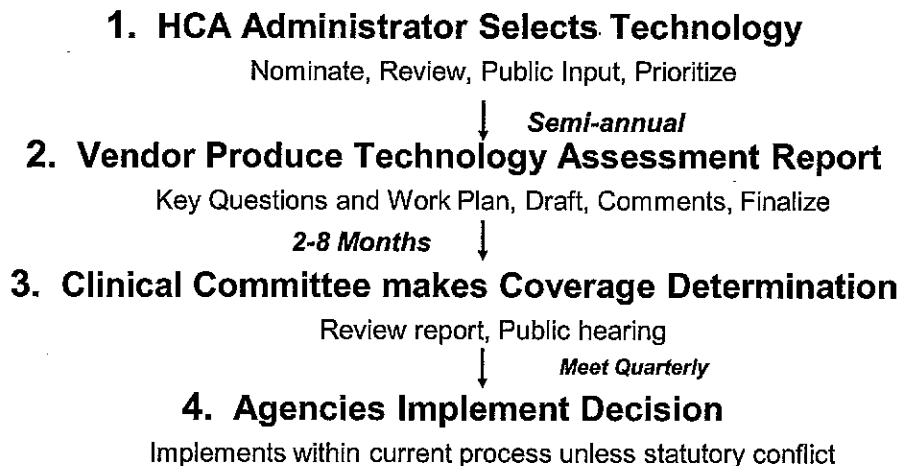
- **Transparency:** Publish topics, criteria, reports, open meeting
- **Technology Assessment Report:** Formal, systematic process to review appropriate healthcare technologies.
- **Independent Coverage decision:** Committee of practicing clinicians make decisions that are scientifically based, transparent, and consistent across state health care purchasing agencies.

Key focus questions:

- Is it safe?
- Is it effective?
- Does it provide value (improve health outcomes)?

4

HTA Program Elements



5

Evidence for use in Policy Decisions

Different Data Sources

- **Efficacy**
 - How technology functions in "best environments"
 - Randomized trials-distinguish technology from other variables
 - Meta-analysis
- **Effectiveness**
 - How technology functions in "real world"
 - Population level analyses
 - Large, multicenter, rigorous, observational cohorts (consecutive pts/objective observers)
- **Safety**
 - Variant of effectiveness
 - Population level analyses
 - Case reports/series, FDA reports
- **Cost**
 - Direct and modeled analysis
 - Cost-effectiveness/utility/benefit studies, modeling
 - Administrative/billing data (charge vs cost)
- **Context**
 - Mix of historic trend, utilization data, beneficiary status, expert opinion

6



Washington State
Health Care Authority

HTCC Decision Basis

- **Clinical Committee Decision must give greatest weight to most valid and reliable evidence**
 - Objective Factors for evidence consideration
 - Nature and Source of evidence
 - Empirical characteristics of the studies or trials upon which evidence is based
 - Consistency of outcomes with comparable studies.
 - Additional evaluation factors
 - Recency (date of information)
 - Relevance (applicability of the information to the key questions presented or participating agency programs and clients)
 - Bias (presence of conflict of interest or political considerations)

WAC 182-55-030: Committee coverage determination process



Washington State
Health Care Authority

***Technology Topics
Underway***

- Sleep Apnea Diagnosis and Treatment
- Bone graft products (autograft, allograft and synthetic)
- Stereotactic Radiosurgery
- Robotic assisted surgical devices (e.g. Davinci, Zeus)
- Upper Endoscopy for GERD
- CT/MR for Pelvic and Abdomen
- Elective Cesarean Section