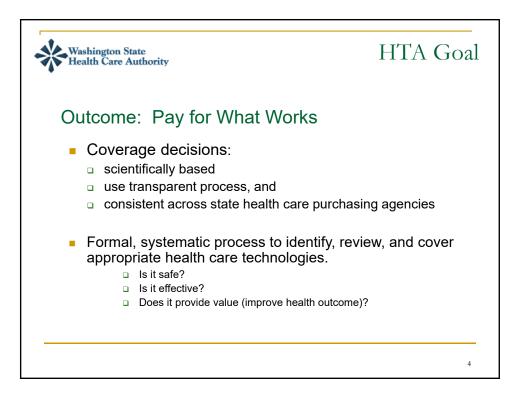


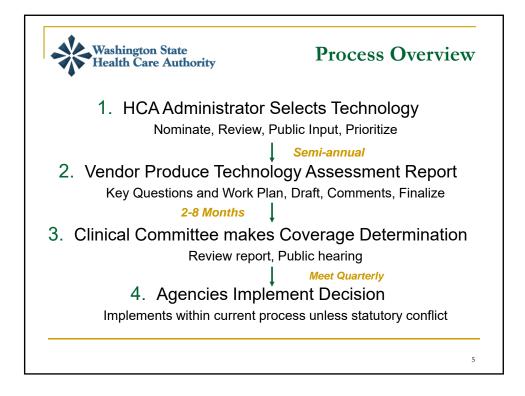
□ Promote <u>consistency</u>: state agencies rely on a single, scientifically based source.

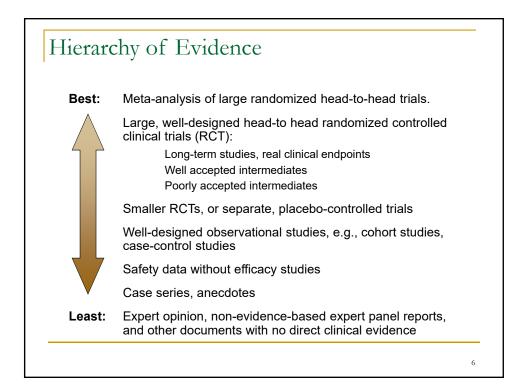
□ <u>Flexible</u>: review evidence regularly to ensure update information is included.

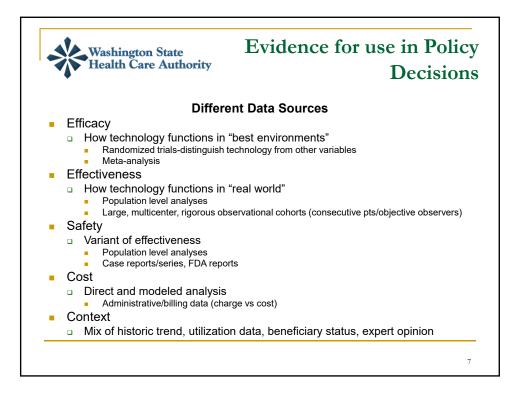
2

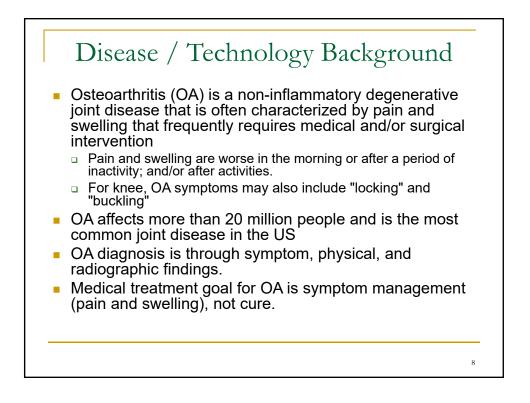


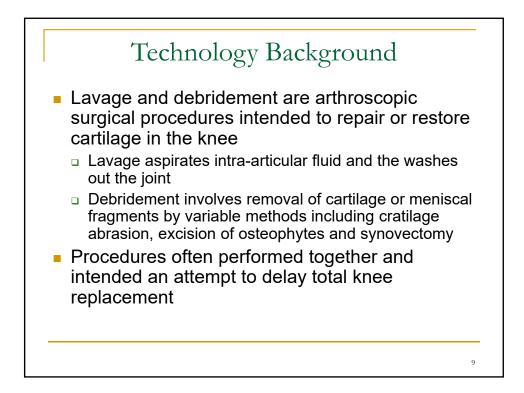


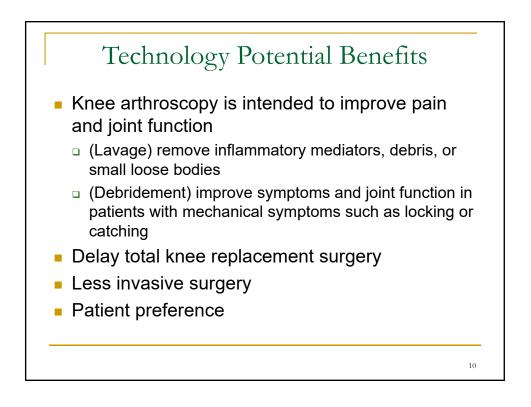


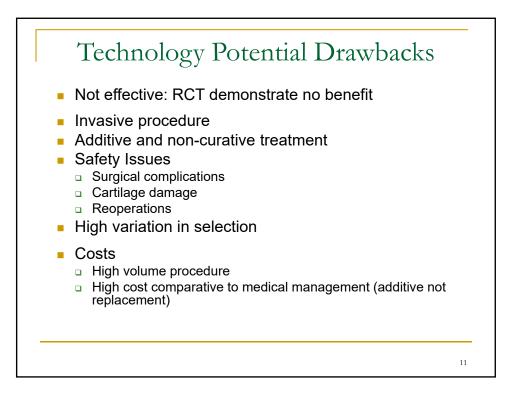


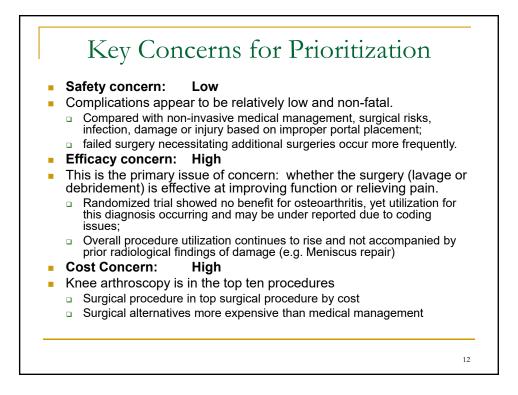


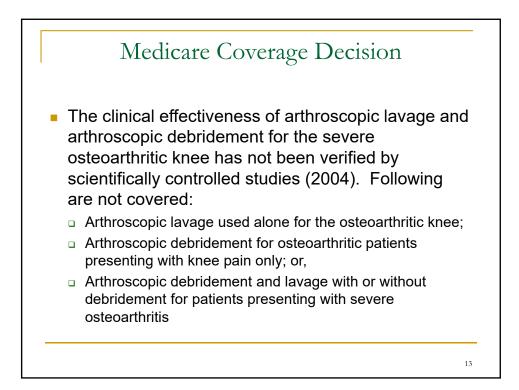




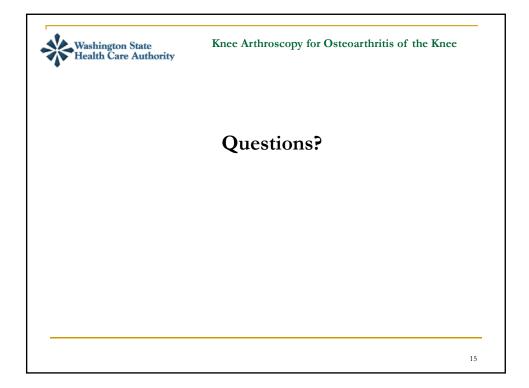


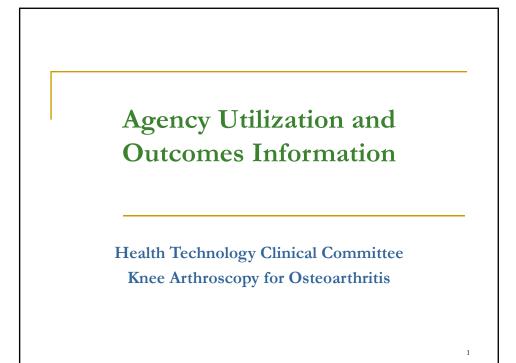


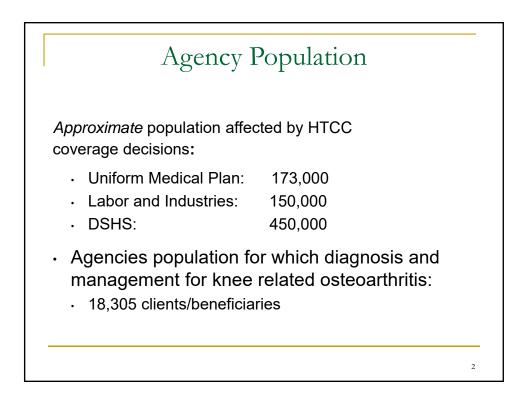




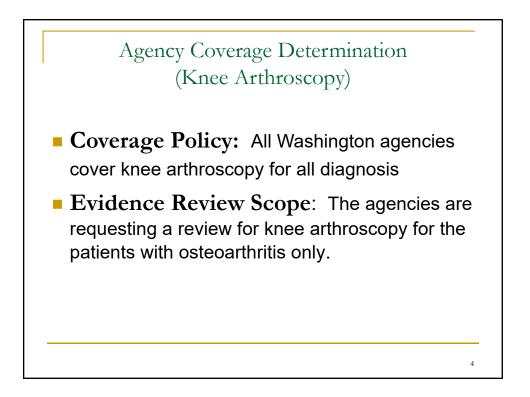
Γ	Specialty Organization Guidelines						
	Osteoarthritis Research Society International- OARSI (Zhang)	2008	"The roles of joint lavage and arthroscopic debridement in knee OA are controversial. Although some studies demonstrated short term symptom relief, others suggest that improvement in symptoms could be attributable to a placebo effect." SOR: 60% (95% CI 47e82)	Y – combin ed evidenc e and consen sus process	Guideline refers to fatally flawed eviden ce		
					14		







shington Agenc	ies popu	lations
State Agencies	Population	Patients with OA claim
Uniform Medical Plan	173,000	8,245
Labor and Industries	150,000	212
Medicaid	450,000	11,337
Tota	al 773,000*	19,794



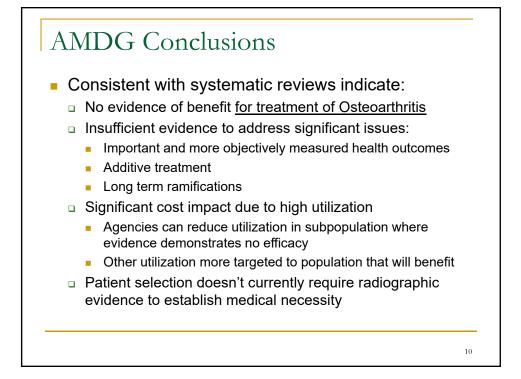


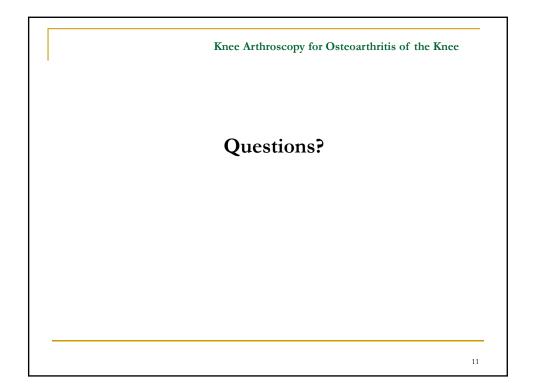


Agency Utilization for Osteoarthritis Services							
Agency administrative claims data for service billed with an osteoarthritis diagnosis. These services include, but are not limited to: Evaluation and Management Services (e.g., office calls, consults) Physical Therapy, Medication Surgery							
Agency SFY 2005 SFY 2006							
Agency			~-	1 2000			
Agency	Patient s	Cost	Patients	Cost			
НСА		Cost \$3,198,413	~ -				
	S		Patients	Cost			
НСА	s 6,637	\$3,198,413	Patients 7,421	Cost \$3,766,993			
HCA L&I	s 6,637 102	\$3,198,413 \$343,389	Patients 7,421 87	Cost \$3,766,993 \$300,989			

Knee Arthroscopy (All Diagnoses)							
The below table outlines agency administrative claims data							
e arthroscopie	es, regardi	ess of diagnose	S.				
Year Procedure Diagnoses Members Paid							
Lavage	All	251	\$406,445				
Debridement	All	4,159	\$12,030,744				
2005 Arthro	scopy Total	4410	\$12,437,189				
Lavage	All	252	\$446,440				
Debridement	All	4,472	\$13,727,466				
2006 Arthro	scopy Total	4724	\$14,173,906				
	v table outlines ee arthroscopie Procedure Lavage Debridement 2005 Arthro Lavage Debridement	Procedure Diagnoses Lavage All All 2005 Arthroscopy Total Image: Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2">Colspan="2"Colspan	Procedure Diagnoses Procedure Diagnoses Members Lavage All 251 Debridement All 4,159 2005 Arthroscopy Total 4410 Lavage All 252 Debridement All 4,472				

(
e (per 1)
2,250
e (per 1)
3,542







State Agency Experience Knee Arthroscopy for Osteoarthritis of the Knee August 15, 2008

Health Technology Assessment

676 Woodland Square Loop SE PO Box 42712 Olympia, WA 98504-2712 Phone 360-923-2742. www.hta.hca.wa.gov



Agency Experience & Background

Osteoarthritis (OA) is a chronic and painful joint disease caused by degeneration that affects more than 20 million people, the most common joint disease in the United States. Knee osteoarthritis causes thinning and softening of the cartilage in the knee that absorbs shock and allows joint surfaces to glide over one another. Medical treatment for osteoarthritis is not curative; it is designed to alleviate symptoms, primarily pain and swelling.

Washington agencies are interested in medical diagnosis and management or treatment services for this serious and painful disease that are safe, effective, and provide value for the health benefit obtained.

In 2006, Washington agencies covered symptom diagnosis and management services for knee related osteoarthritis for 18,305 clients/beneficiaries. These services vary by agency and include:

- Physician visits (evaluation and maintenance)
- Physical therapy/occupational therapy
- Massage
- Acupuncture
- Pharmacotherapy (oral medication)
- Injections
- Durable medical equipment and supplies
- Radiology (x-ray, MRI)
- Surgery knee replacement, knee arthroscopy

<u>Note</u>: "Washington agencies" in this analysis refers to the Health Care Authority, Department of Social and Health Services, and Labor and Industries.

Knee arthroscopy is in the top ten procedures, by cost, that are paid for by the Washington agencies. (For DSHS, orthopedic surgeries are number four and include knee arthroscopy). This surgical procedure is generally performed to directly visualize the knee joint, remove excess fluids and worn or loose bodies and repair tears. It is regarded as minimally invasive and a generally safe surgery that has effectiveness in treating certain knee injuries.

One of the reasons for performing arthroscopic knee surgery is to reduce pain in patients with osteoarthritis. However, important clinical questions about the effectiveness of knee arthroscopy for osteoarthritis are present and nationally there is wide variation in its use for this and other conditions.

All three agencies cover knee arthroscopy, including lavage and debridement. The Health Care Authority currently has no restrictions; the Department of Health and Social Services has a prior authorization requirement on one procedure code (29877 Chondroplasty) only, but no listed prior authorization conditions. Labor and Industries has a medical policy for all knee surgeries (not limited or segregated by diagnosis) that places some conservative treatment and findings requirements on knee surgeries. (see attachment one).



Prioritization concerns and technology ranking

Arthroscopic surgery of the knee for Osteoarthritis

• Safety concern: Low

Complications appear to be relatively low and non-fatal.

• Compared with non-invasive medical management, surgical risks, infection, damage or injury based on improper portal placement; and failed surgery necessitating additional surgeries occur more frequently.

• Efficacy concern: High

This is the primary issue of concern: whether the surgery (lavage or debridement) is effective at improving function or relieving pain.

- Randomized trial showed no benefit for osteoarthritis, yet utilization for this diagnosis occurring and may be under reported due to coding issues;
- Overall procedure utilization continues to rise and not accompanied by prior radiological findings of damage (e.g. Meniscus repair)

• Cost Concern: High

Knee arthroscopy is in the top ten procedures

- Surgical procedure in top surgical procedure by cost
- o Surgical alternatives more expensive than medical management

Medicare National Coverage Decision – For osteoarthritis of the knee, Medicare has made a national non-coverage decision for certain indications only. Arthroscopic lavaage is not covered; arthroscopic debridement for individuals presenting with pain only is not covered; and arthroscopic debridement and lavage with or without debridement for patients with severe osteoarthritis is not covered. All other indications are subject to local discretion. (see attachment two).

State Agency Experience

Overall Washington Agencies population upon which utilization information is drawn

State Agencies	Population	Patients with OA claim
Uniform Medical Plan	173,000	8,245
Labor and Industries	150,000	212
Medicaid	450,000	11,337
Total	773,000*	19,794

*Population figures fluctuate and agency direct purchasing totals are at least this level. Patients with any Osteoarthritis claim numbers are from State Fiscal Year 2006.

Context: Washington Agency Utilization – All Knee Arthroscopy

Although the HTCC will be looking only at knee arthroscopy as it relates to osteoarthritis of the knee, the agencies wanted to provide context of total utilization for persons receiving knee arthroscopy. The following table shows state utilization for SFY 2005 and SFY 2006 broken down by lavage and debridement and includes all charges on the day of surgery.

Year	Procedure	Diagnoses	Members	Paid
2005	Lavage	All	251	\$406,445
2005	Debridement	All	4,159	\$12,030,744
	2005 Arthros	scopy Total	4410	\$12,437,189
2006	Lavage	All	252	\$446,440
2006	Debridement	All	4,472	\$13,727,466
	2006 Arthros	scopy Total	4724	\$14,173,906

Context: Washington Agency Utilization of Knee Osteoarthritis Services

The table below provides information on the number of patients seeking medical services for osteoarthritis of the knee and the total costs for services associated with osteoarthritis care for these patients. A more detailed breakdown of costs for knee osteoarthritis patients for L&I and HCA follows this table. Pharmacy costs are separately reported because they include on HCA and L&I costs, not HRSA

Agency	SF	Y 2005	SI	FY 2006
	Patients	Cost	Patients	Cost
НСА	6,637	\$3,198,413	7,421	\$3,766,993
L&I	102	\$343,389	87	\$300,989
DSHS	10,258	\$2,461,920	10,797	\$2,591,280
Pharmacy (L&I/HCA)		\$18,201,852		\$19,139,000
Totals Agencies Patients & Cost*	16,997	\$24,205,574	18,305	\$25,798,262

As noted above, total cost does not include DSHS pharmacy data



Context: Medical Services detail for osteoarthritis of the knee

There are a variety of medical services that are believed to be beneficial to patients who have osteoarthritis of the knee. The below table shows medical services by units of services and cost utilized by <u>L&I and HCA</u> patients where diagnoses on the claims was for osteoarthritis of the knee. This detailed table does not contain DSHS (Medicaid) utilization information.

SFY 2005		
Categories	Units of Service	Cost
**Physical/Massage/Occupational Therapy	26,324	\$867,752
Alternative Care	813	\$12,982
DME/Supplies	1,115	\$177,046
Injections	2,868	\$192,634
Radiology	6,544	\$661,638
Knee Replacement Surgery	3	\$4,346
Basic E&M Services	8,122	\$375,394
All Other Medical Services	4,425	\$1,153,958
*Pharmacy	23,194	\$18,201,852
Total Cost	73,408	\$21,647,602
SFY 2006		
Category	Units of Service	Cost
		Cost \$1,019,087
Category	Service	
Category **Physical/Massage/Occupational Therapy	Service 30,097	\$1,019,087
Category **Physical/Massage/Occupational Therapy Alternative Care	Service 30,097 2,007	\$1,019,087 \$39,702
Category **Physical/Massage/Occupational Therapy Alternative Care DME/Supplies	Service 30,097 2,007 1,074	\$1,019,087 \$39,702 \$164,556
Category**Physical/Massage/Occupational TherapyAlternative CareDME/SuppliesInjections	Service 30,097 2,007 1,074 3,114	\$1,019,087 \$39,702 \$164,556 \$220,968
Category**Physical/Massage/Occupational TherapyAlternative CareDME/SuppliesInjectionsRadiology	Service 30,097 2,007 1,074 3,114 6,729	\$1,019,087 \$39,702 \$164,556 \$220,968 \$791,928
Category**Physical/Massage/Occupational TherapyAlternative CareDME/SuppliesInjectionsRadiologyKnee Replacement	Service 30,097 2,007 1,074 3,114 6,729 2	\$1,019,087 \$39,702 \$164,556 \$220,968 \$791,928 \$2,430
Category**Physical/Massage/Occupational TherapyAlternative CareDME/SuppliesInjectionsRadiologyKnee ReplacementBasic E&M Services	Service 30,097 2,007 1,074 3,114 6,729 2 2 7,874	\$1,019,087 \$39,702 \$164,556 \$220,968 \$791,928 \$2,430 \$434,417
Category**Physical/Massage/Occupational TherapyAlternative CareDME/SuppliesInjectionsRadiologyKnee ReplacementBasic E&M ServicesAll Other Medical Services	Service 30,097 2,007 1,074 3,114 6,729 2 7,874 7,662	\$1,019,087 \$39,702 \$164,556 \$220,968 \$791,928 \$2,430 \$434,417 \$1,313,577



Agency Utilization: Knee Arthroscopy for Osteoarthritis

The following table shows the Washington state agencies utilization and costs for patients who had knee arthroscopy specifically for osteoarthritis of the knee.

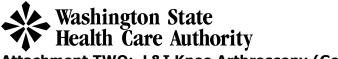
Year	Procedure	Diagnoses	Members	Paid	Cost Range (per person)
2005	Lavage	Osteoarthritis	14	\$27,659	
2006	Lavage	Osteoarthritis	18	\$37,296	\$1,975 - \$2,250
					Cost Range (per
Year	Procedure	Diagnosis	Members	Cost	person)
2005	Debridement	Osteoarthritis	143	\$437,666	
2006	Debridement	Osteoarthritis	108	\$331,488	\$2,800 - \$3,542

Attachment ONE: Knee Arthroscopy Procedure Codes

The table below outlines the procedure codes used in the identification of knee arthroscopy services.

Knee Arthroscopy Procedure Codes			
Procedure Code	Procedure Code		
29870 (Diagnostic)	29881 (Menisectomy, medial or lateral)		
29871 (Lavage)	29882 (Meniscus repair, medial and lateral)		
29873 (Lateral Release)	29883 (Meniscus repair, medial or lateral		
29874 (Removal lose/foreign bodies)	29884 (Lysis of lesions)		
29875 (Synovectomy, limited)	29885 (Drilling for osteochondritis dissecan)		
29876 (Synovectomy, major	29886 (Drilling for intact osteochonidritis)		
29877 (Chondroplasty)	29887 (Drill for intact osteochonidritis with internal		
	fixation)		
29879 (Abrasion arthroplasty)	29888 (Arthroscopic ligament anterior repair)		
29880 (menisectomy, medical and lateral)	29889 (Arthroscopic ligament posterior repair		

*Although G0289 is coded for arthroscopy of the knee, it is an "add on" code that will be caught within the surgical codes listed above.



Attachment TWO: L&I Knee Arthroscopy (General)

Medical Treatment Guidelines

Washington State Department of Labor and Industries

Procedure	Conservative care	Subjective	Objective	Imaging
Diagnostic arthroscopy.	Medications. OR Physical therapy. AND	Pain and functional limitations continue despite conservative care.	AND	Imaging is inconclusive.
Meniscectomy or meniscus repair.	(Not required for locked/blocked knee). Physical therapy. OR Medication. OR Activity modification. AND	Joint pain. OR Swelling. OR Feeling of give way. OR Locking, clicking, or popping. AND	Positive Mc Murray's sign. OR Joint line tenderness. OR Effusion. OR Limited range of motion. OR Locking, clicking, or popping. OR Crepitus. AND	(Not required for locked/blocked knee). Meniscal tear on MRI.
Chondroplasty (Shaving or debridement of an articular surface).	Medication. OR Physical therapy. AND	Joint pain. AND Swelling. AND	Effusion. OR Crepitus OR Limited ROM	



ATTACHMENT THREE: CMS Coverage Decision

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=150.9&ncd_version=1&basket=ncd%3A150%2E9%3A1%3AArthroscopi c+Lavage+and+Arthroscopic+Debridement+for+the+Osteoarthritic+Knee

NCD for Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee

A. <u>Nationally Covered Indications</u>

Not applicable.

B. Nationally Noncovered Indications

The clinical effectiveness of arthroscopic lavage and arthroscopic debridement for the severe osteoarthritic knee has not been verified by scientifically controlled studies. After thorough discussions with clinical investigators, the orthopedic community, and other interested parties, CMS determines that the following procedures are not considered reasonable or necessary in treatment of the osteoarthritic knee and are not covered by the Medicare program:

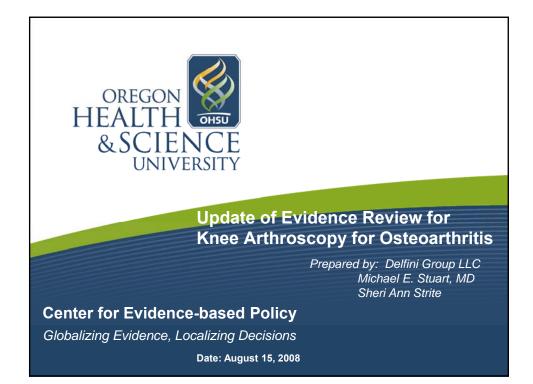
- Arthroscopic lavage used alone for the osteoarthritic knee;
- Arthroscopic debridement for osteoarthritic patients presenting with knee pain only; or,
- Arthroscopic debridement and lavage with or without debridement for patients presenting with severe osteoarthritis ((Severe osteoarthritis is defined in the Outerbridge classification scale, grades III and IV. Outerbridge is the most commonly used clinical scale that classifies the severity of joint degeneration of the knee by compartments and grades. Grade I is defined as softening or blistering of joint cartilage. Grade II is defined as fragmentation or fissuring in an area <1 cm. Grade III presents clinically with cartilage fragmentation or fissuring in an area >1 cm. Grade IV refers to cartilage erosion down to the bone. Grades III and IV are characteristic of severe osteoarthritis.)

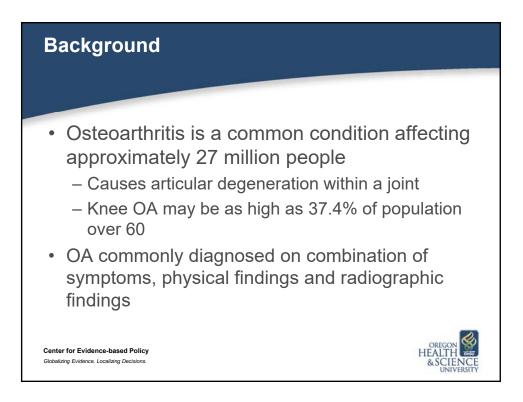
C. <u>Other</u>

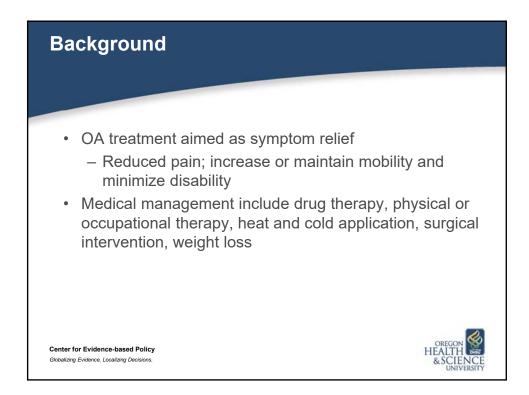
Apart from the noncovered indications above for arthroscopic lavage and/or arthroscopic debridement of the osteoarthritic knee, all other indications of debridement for the subpopulation of patients without severe osteoarthritis of the knee who present with symptoms other than pain alone; i.e., (1) mechanical symptoms that include, but are not limited to, locking, snapping, or popping (2) limb and knee joint alignment, and (3) less severe and/or early degenerative arthritis, remain at local contractor discretion. Medicare contractors may require submission of one or all of the following documents to define the patient's knee condition:

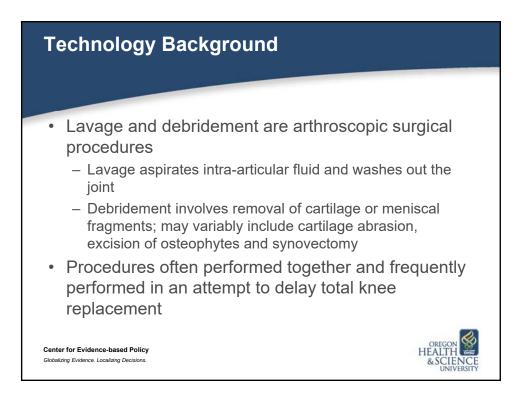
- Operative notes,
- Reports of standing x-rays, or,
- Arthroscopy results.

(This NCD last reviewed June 2004.)

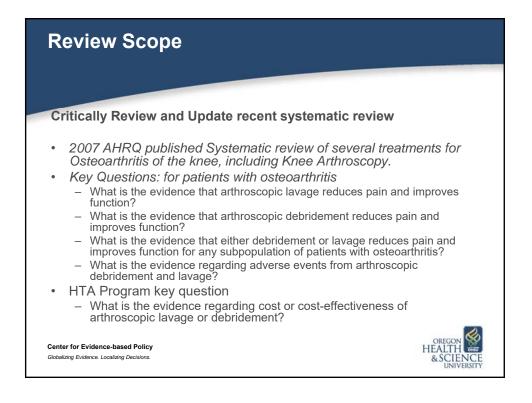












Search Methods / Results

Search Approach

Critical Appraisal of the systematic review published by AHRQ conducted by Blue Cross and Blue Shield Technology Evaluation Center (Samson, 2007)

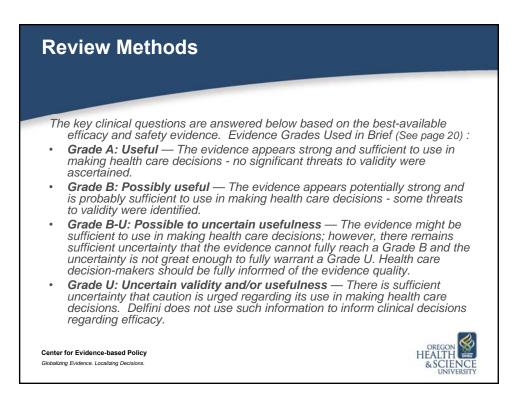
 Update: Literature search for additional systematic reviews and trials on safety and efficacy of arthroscopic debridement and lavage for knee osteoarthritis published after search date. Literature search for cost effectiveness analysis and review and summary of cost policies and treatment guidelines

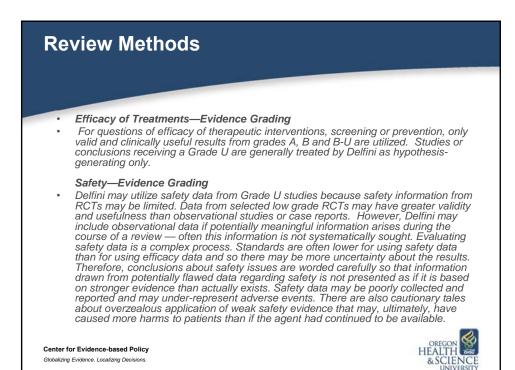
Search Results

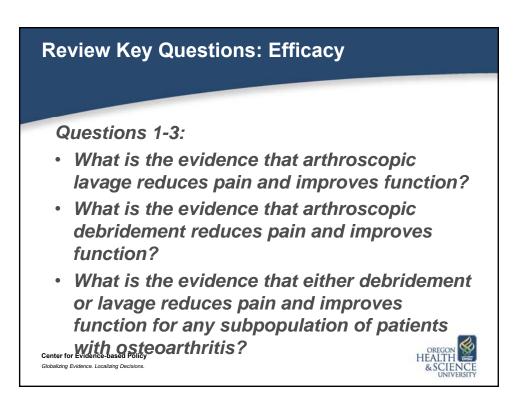
- Efficacy: 31 articles retrieved for potential inclusion
- Safety: 9 articles retrieved for potential inclusion
- Cost analysis: 0 articles

Evidence Base included for Critical Appraisal

- AHRQ Publication (Samson 2007)
- Cochrane Review (Laupattarakasem 2008)
- Osteoarthritis Research Society International Recommendations (Zhang 2008)







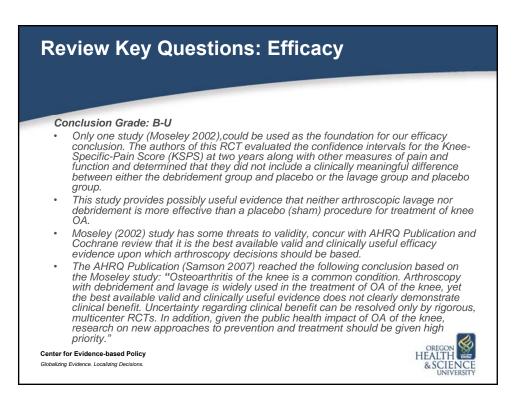
Review Key Questions: Efficacy

Conclusion Grade: B-U

- AHRQ Publication Findings: We agree with the authors of the AHRQ publication's efficacy conclusions that the evidence is insufficient to conclude that arthroscopy and lavage or debridement for treatment of osteoarthritis of the knee results in pain reduction or improved function for patients. This includes any subgroups of patients.
- Review and Update Findings: Neither arthroscopic lavage nor debridement have been found to be superior to sham arthroscopy in well-designed and conducted randomized controlled trials (RCTs).

HEALTH

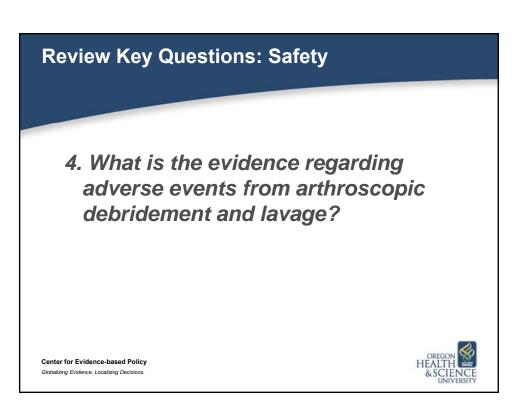
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Review Key Questions: Efficacy

Conclusion Grade: B-U

- **Possible to uncertain usefulness** The evidence might be sufficient to use in making health care decisions; however, there remains sufficient uncertainty that the evidence cannot fully reach a Grade B and the uncertainty is not great enough to fully warrant a Grade U. Health care decision-makers should be fully informed of the evidence quality.
- Reason for Grade
- Conclusion is based on a single RCT.
- The single RCT was graded B-U due to some threats to validity.



Review Key Questions: Safety

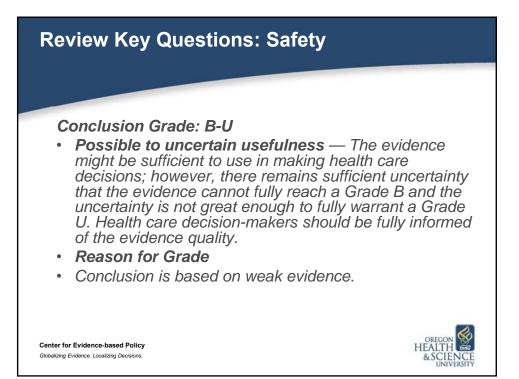
Conclusion Grade: B-U

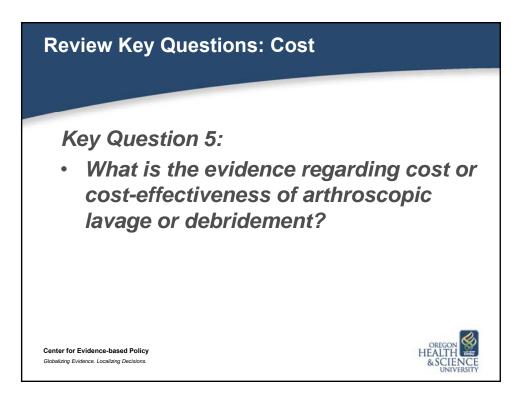
- AHRQ Publication Findings: The AHRQ publication reported extensive safety data from observational studies (see below). As mentioned in the AHRQ publication, confidence in the accuracy of adverse events data is extremely low when it is derived from observational studies. Observational data, however, provide useful indicators that should raise end users' awareness about safety concerns
- Review and Update Findings: We found only Grade U study (uncertain efficacy and usefulness) information on adverse effects from RCTs evaluating arthroscopy with lavage and debridement for knee OA primarily because the trials focused on efficacy and did not formally measure safety events. RCT and observational data of uncertain validity and usefulness (Grade U), however, provide some indications about safety that should raise end users' awareness about potential harms. (Anesthesia risk information is not included in assessment below.) Center for Evidence-based Policy Ś OREGON HEALTH

& SCIENCE

Globalizing Evidence. Localizing Decisions.

Review Key Questions: Safety					
Conclusion Grade: B-U					
Complication	Frequency	Source			
Mortality	0.1% to 0.5%	Samson 2007			
Stroke or MI	0.3%	Samson 2007			
DVT	0.6% to 17.9%	Ramos 2007			
Hemarthrosis	Up to 25%	Samson 2007			
Infection	0.5% to 2%	Samson 2007			
enter for Evidence-based Policy					





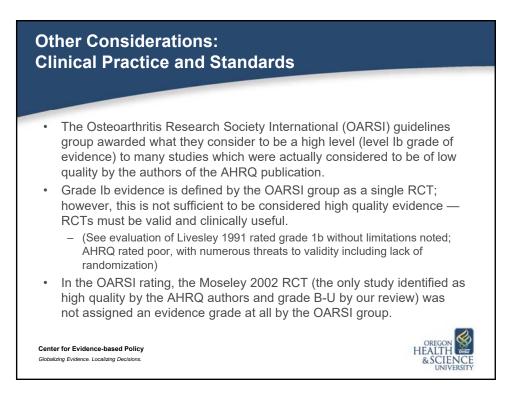
Review Key Questions: Cost

Conclusion

- AHRQ Publication Findings: The AHRQ publication did not address the issue of cost or cost-effectiveness.
- **Review and Update Findings**: We found only Grade U study (uncertain efficacy and usefulness) information on cost and cost-effectiveness. As noted below, this is likely because effectiveness has not yet been demonstrated.
- No useful economic modeling information was found in our MEDLINE searches.
- An economic model was provided by The Medical Advisory Secretariat Ministry of Health and Long-Term Care, Toronto. The authors were unable to conduct a full economic analysis because effectiveness was not demonstrated in the literature. They state that based on the Moseley (2002) trial, cost effectiveness is likely to be unfavorable. However, they provide an outline of considerations (e.g., hospital costs, non-hospital costs, discounting, etc. that may be useful in creating an economic model to inform cost estimates.

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Other Considerations: Clinical Practice and Standards

- AD and lavage for OA of the knee are performed with great frequency, reported by Moseley (2002) to be approximately 650,000 per year in 1998, yet despite this frequency they remain controversial even among experts within the orthopedic community.
- OARSI guidelines:
 - The roles of joint lavage and arthroscopic debridement in knee OA are controversial. Although some studies have demonstrated short-term symptom relief, others suggest that improvement in symptoms could be attributable to a placebo effect."
- Strength of recommendations by the guideline team on a scale of 0 to 100 (100 being strongest) was over 90 for weight loss, non-steroidal anti-inflammatory drugs, acetaminophen and total knee replacement, but only 60 for lavage and arthroscopic debridement. Controversy is frequent when there is uncertainty.

Center for Evidence-based Policy Globalizing Evidence. Localizing Decisions.

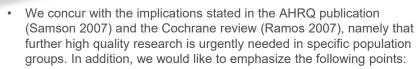


Other Considerations: Patient Implications

- When substantial benefits for patients have not been demonstrated through valid RCTs, it is imperative for patients and others to be appropriately informed of the uncertainty, potential harmful effects of an intervention along with the concomitant interventions that accompany it.
- There is one case series, included in the AHRQ publication which reported 90% patient satisfaction with symptom and function with a mean follow-up of approximately 4 years.
- We found three case series reporting satisfaction. Overall, 63.2% (129 knees) were better, 21.1% (43 knees) were unchanged, and 15.7% (32 knees) were worse after surgery.
- The validity and usefulness of these case series are severely limited by the numerous confounders and biases present in case series including lack of comparison group, lack of blinding, placebo effect,







- To demonstrate that an intervention is likely to improve patients' health or quality of life requires valid evidence that meaningful patient benefits outweigh harms.
- Low quality evidence or clinical experience is insufficient for demonstrating improved patient outcomes and may result in significant harms and costs.
- There is an urgent need for additional double-blind RCTs of arthroscopic lavage and debridement in various patient groups with OA of the knee



HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

- 1. Is it safe?
- 2. Is it effective?
- 3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective¹ as expressed by the following standards.²

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.³

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

¹ Based on Legislative mandate: See RCW 70.14.100(2).

² The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

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Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence⁴ using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident	
Appreciable uncertainty exists. Further	Very certain of evidentiary support.	
information is needed or further	Further information is unlikely to change	
information is likely to change confidence.	confidence	

3. Factors for Consideration - Importance

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

⁴ Based on GRADE recommendation: <u>http://www.gradeworkinggroup.org/FAQ/index.htm</u>

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

Safety Outcomes	Safety Evidence
Mortality	ě
Morbidity	
- Stroke/MI	
- DVT	
- Hemarthrosis	
- Infection	
- Nerve/tissue damage	
Efficacy/Effectiveness Outcomes	Efficacy/Effectiveness Evidence
Pain Relief:	
Short/Long term	
Magnitude of relief	
Direct or surrogate measure(s)	
Improves Function	
Short/Long term	
Magnitude of relief	
Direct or surrogate measure(s)	
Return to Work	
Cost Outcomes	Cost Evidence
Cost Outcomes	Cost Evidence
Other Factors	Evidence
Durability of result	Evidence

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	2004	No coverage for: lavage alone debridement for patients with knee pain only debridement and lavage with or without debridement for patients with severe osteoarthritis 	Y	Not Rated
Osteoarthritis Research Society International-OARSI (Zhang)	2008	"The roles of joint lavage and arthroscopic debridement in knee OA are controversial. Although some studies demonstrated short term symptom relief, others suggest that improvement in symptoms could be attributable to a placebo effect." SOR: 60% (95% CI 47e82)	Y – combined evidence and consensus process	Guideline refers to fatally flawed evidence

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Inconclusive (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not costeffective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and costeffective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____Not covered. _____Covered Unconditionally. _____Covered under certain conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover With Conditions

If covered with conditions, the Committee will continue discussions.

1) Does the committee have enough information to identify conditions or criteria?

- Refer to evidence identification document and discussion.
- Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
- Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meting.
- 2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
 - What are the known conditions/criteria and evidence state
 - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
 - Direct outcome or surrogate measure
 - Short term or long term effect
 - Magnitude of effect
 - Impact on pain, functional restoration, quality of life
 - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
 - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

<u>Safety</u>

- What is the evidence of the effect of using the technology on significant morbidity?
 - Frequent adverse effect on health, but unlikely to result in lasting harm or be lifethreatening, or;
 - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality does it result in fewer adverse non-fatal outcomes?

Cost Impact

• Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

<u>Overall</u>

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?