



Health Technology Assessment Program

Health Technology Clinical Committee
Knee Arthroscopy for Osteoarthritis of the Knee

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Washington's Health Technology Assessment Program Background

- Part of Governor's 2006 Five point health strategy for state to lead by example
 - Emphasize evidence-based health care
<http://www.hca.wa.gov/conf/contf/doc/GovGregoireHealthBrief.pdf>
- Program Purpose: Achieve better health by paying for technologies that work
 - Better health with better information: investigate what works and maintain a centralized website.
 - Open and transparent process: publish process, criteria, reports, and committee decisions in public meeting.
 - Eliminate Bias: contract for independent evidence report and independent clinical committee.
 - Promote consistency: state agencies rely on a single, scientifically based source.
 - Flexible: review evidence regularly to ensure update information is included.

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Why Health Technology

Health Care Context

- **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*
- **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

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HTA Goal

Outcome: Pay for What Works

- **Coverage decisions:**
 - scientifically based
 - use transparent process, and
 - consistent across state health care purchasing agencies
- **Formal, systematic process to identify, review, and cover appropriate health care technologies.**
 - Is it safe?
 - Is it effective?
 - Does it provide value (improve health outcome)?

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1. HCA Administrator Selects Technology
Nominate, Review, Public Input, Prioritize
↓ *Semi-annual*
2. Vendor Produce Technology Assessment Report
Key Questions and Work Plan, Draft, Comments, Finalize
2-8 Months ↓
3. Clinical Committee makes Coverage Determination
Review report, Public hearing
↓ *Meet Quarterly*
4. Agencies Implement Decision
Implements within current process unless statutory conflict

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Hierarchy of Evidence

- Best:** Meta-analysis of large randomized head-to-head trials.
- Large, well-designed head-to head randomized controlled clinical trials (RCT):
- Long-term studies, real clinical endpoints
 - Well accepted intermediates
 - Poorly accepted intermediates
- Smaller RCTs, or separate, placebo-controlled trials
- Well-designed observational studies, e.g., cohort studies, case-control studies
- Safety data without efficacy studies
- Case series, anecdotes
- Least:** Expert opinion, non-evidence-based expert panel reports, and other documents with no direct clinical evidence

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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
 - Administrative/billing data (charge vs cost)
- Context
 - Mix of historic trend, utilization data, beneficiary status, expert opinion

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Disease / Technology Background

- Osteoarthritis (OA) is a non-inflammatory degenerative joint disease that is often characterized by pain and swelling that frequently requires medical and/or surgical intervention
 - Pain and swelling are worse in the morning or after a period of inactivity; and/or after activities.
 - For knee, OA symptoms may also include "locking" and "buckling"
- OA affects more than 20 million people and is the most common joint disease in the US
- OA diagnosis is through symptom, physical, and radiographic findings.
- Medical treatment goal for OA is symptom management (pain and swelling), not cure.

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Technology Background

- Lavage and debridement are arthroscopic surgical procedures intended to repair or restore cartilage in the knee
 - Lavage aspirates intra-articular fluid and the washes out the joint
 - Debridement involves removal of cartilage or meniscal fragments by variable methods including cartilage abrasion, excision of osteophytes and synovectomy
- Procedures often performed together and intended an attempt to delay total knee replacement

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Technology Potential Benefits

- Knee arthroscopy is intended to improve pain and joint function
 - (Lavage) remove inflammatory mediators, debris, or small loose bodies
 - (Debridement) improve symptoms and joint function in patients with mechanical symptoms such as locking or catching
- Delay total knee replacement surgery
- Less invasive surgery
- Patient preference

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Technology Potential Drawbacks

- Not effective: RCT demonstrate no benefit
- Invasive procedure
- Additive and non-curative treatment
- Safety Issues
 - Surgical complications
 - Cartilage damage
 - Reoperations
- High variation in selection
- Costs
 - High volume procedure
 - High cost comparative to medical management (additive not replacement)

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Key Concerns for Prioritization

- **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;
 - 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
 - Surgical alternatives more expensive than medical management

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Medicare Coverage Decision

- The clinical effectiveness of arthroscopic lavage and arthroscopic debridement for the severe osteoarthritic knee has not been verified by scientifically controlled studies (2004). Following are not covered:
 - 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

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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 – combined evidence and consensus process	Guideline refers to fatally flawed evidence
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Questions?

Agency Utilization and Outcomes Information

Health Technology Clinical Committee
Knee Arthroscopy for Osteoarthritis

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Agency Population

Approximate population affected by HTCC coverage decisions:

- Uniform Medical Plan: 173,000
- Labor and Industries: 150,000
- DSHS: 450,000
- Agencies population for which diagnosis and management for knee related osteoarthritis:
 - 18,305 clients/beneficiaries

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Agency Population

Washington Agencies populations

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.*

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Agency Coverage Determination (Knee Arthroscopy)

- **Coverage Policy:** All Washington agencies cover knee arthroscopy for all diagnosis
- **Evidence Review Scope:** The agencies are requesting a review for knee arthroscopy for the patients with osteoarthritis only.

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State Agency Coverage Policy

■ Coverage Alternatives:

- The agencies cover alternatives,
- Coverage varies by agency but includes:
 - Medications (Acetaminophen, NSAID, etc.)
 - Rehabilitation
 - Physical Therapy
 - Psychological
 - Exercise, education
 - Interdisciplinary Rehabilitation
 - Alternative and Complimentary medicine (massage, acupuncture)
 - Surgical: Total Knee Replacement

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Key Concerns for Prioritization

- **Safety concern: Low**
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 - Compared with non-invasive medical management, surgical risks, infection, damage or injury based on improper portal placement;
 - failed surgery necessitating additional surgeries occur more frequently.
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- 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
 - Surgical alternatives more expensive than medical management

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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	
	Patients	Cost	Patients	Cost
HCA	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

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Knee Arthroscopy (All Diagnoses)

The below table outlines agency administrative claims data for all knee arthroscopies, regardless of diagnoses.

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

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Knee Arthroscopy for Osteoarthritis of the Knee

The below table outlines combined agency administrative claims data for all knee arthroscopies for osteoarthritis of the knee.

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

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AMDG Conclusions

- Consistent with systematic reviews indicate:
 - No evidence of benefit for treatment of Osteoarthritis
 - Insufficient evidence to address significant issues:
 - Important and more objectively measured health outcomes
 - Additive treatment
 - Long term ramifications
 - Significant cost impact due to high utilization
 - Agencies can reduce utilization in subpopulation where evidence demonstrates no efficacy
 - Other utilization more targeted to population that will benefit
 - Patient selection doesn't currently require radiographic evidence to establish medical necessity

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Questions?



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

Health Technology Assessment

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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

Note: "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
- 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 lavage 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 Arthroscopy Total			4410	\$12,437,189
2006	Lavage	All	252	\$446,440
2006	Debridement	All	4,472	\$13,727,466
2006 Arthroscopy 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	SFY 2005		SFY 2006	
	Patients	Cost	Patients	Cost
HCA	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 L&I and HCA 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
**Physical/Massage/Occupational Therapy	30,097	\$1,019,087
Alternative Care	2,007	\$39,702
DME/Supplies	1,074	\$164,556
Injections	3,114	\$220,968
Radiology	6,729	\$791,928
Knee Replacement	2	\$2,430
Basic E&M Services	7,874	\$434,417
All Other Medical Services	7,662	\$1,313,577
Tens Unit	4	\$158.40
*Pharmacy	28,512	\$19,139,000
Total	87,075	\$23,125,823

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

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 (Meniscectomy, medial or lateral)
29871 (Lavage)	29882 (Meniscus repair, medial and lateral)
29873 (Lateral Release)	29883 (Meniscus repair, medial or lateral)
29874 (Removal loose/foreign bodies)	29884 (Lysis of lesions)
29875 (Synovectomy, limited)	29885 (Drilling for osteochondritis dissecan)
29876 (Synovectomy, major)	29886 (Drilling for intact osteochondritis)
29877 (Chondroplasty)	29887 (Drill for intact osteochondritis with internal fixation)
29879 (Abrasion arthroplasty)	29888 (Arthroscopic ligament anterior repair)
29880 (meniscectomy, medial 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.

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.
Menisectomy 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%3AArthroscopic+Lavage+and+Arthroscopic+Debridement+for+the+Osteoarthritic+Knee

NCD for Arthroscopic Lavage and Arthroscopic Debridement for the Osteoarthritic Knee**A. Nationally Covered Indications**

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. Other

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.)



Update of Evidence Review for Knee Arthroscopy for Osteoarthritis

*Prepared by: Delfini Group LLC
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Center for Evidence-based Policy

Globalizing Evidence, Localizing Decisions

Date: August 15, 2008

Background

- Osteoarthritis is a common condition affecting approximately 27 million people
 - Causes articular degeneration within a joint
 - Knee OA may be as high as 37.4% of population over 60
- OA commonly diagnosed on combination of symptoms, physical findings and radiographic findings

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Background

- OA treatment aimed as symptom relief
 - Reduced pain; increase or maintain mobility and minimize disability
- Medical management include drug therapy, physical or occupational therapy, heat and cold application, surgical intervention, weight loss

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Technology Background

- Lavage and debridement are arthroscopic surgical procedures
 - Lavage aspirates intra-articular fluid and washes out the joint
 - Debridement involves removal of cartilage or meniscal fragments; may variably include cartilage abrasion, excision of osteophytes and synovectomy
- Procedures often performed together and frequently performed in an attempt to delay total knee replacement

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Context Background

- Knee arthroscopy is high volume and high cost intervention (650,000 procedures in US in 1998)
- Controversial efficacy for OA
- Surgical procedure is minimally invasive surgery but has clinically significant adverse events (DVT, infection)

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Review Scope

Critically Review and Update recent systematic review

- 2007 AHRQ published Systematic review of several treatments for Osteoarthritis of the knee, including Knee Arthroscopy.
- Key Questions: for patients with osteoarthritis
 - What is the evidence that arthroscopic lavage reduces pain and improves function?
 - What is the evidence that arthroscopic debridement reduces pain and improves function?
 - What is the evidence that either debridement or lavage reduces pain and improves function for any subpopulation of patients with osteoarthritis?
 - What is the evidence regarding adverse events from arthroscopic debridement and lavage?
- HTA Program key question
 - What is the evidence regarding cost or cost-effectiveness of arthroscopic lavage or debridement?

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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)

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Review Methods

The key clinical questions are answered below based on the best-available efficacy and safety evidence. Evidence Grades Used in Brief (See page 20) :

- **Grade A: Useful** — *The evidence appears strong and sufficient to use in making health care decisions - no significant threats to validity were ascertained.*
- **Grade B: Possibly useful** — *The evidence appears potentially strong and is probably sufficient to use in making health care decisions - some threats to validity were identified.*
- **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.*
- **Grade U: Uncertain validity and/or usefulness** — *There is sufficient uncertainty that caution is urged regarding its use in making health care decisions. Delfini does not use such information to inform clinical decisions regarding efficacy.*

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Review Methods

- **Efficacy of Treatments—Evidence Grading**
- For questions of efficacy of therapeutic interventions, screening or prevention, only valid and clinically useful results from grades A, B and B-U are utilized. Studies or conclusions receiving a Grade U are generally treated by Delfini as hypothesis-generating only.
- **Safety—Evidence Grading**
- Delfini may utilize safety data from Grade U studies because safety information from RCTs may be limited. Data from selected low grade RCTs may have greater validity and usefulness than observational studies or case reports. However, Delfini may include observational data if potentially meaningful information arises during the course of a review — often this information is not systematically sought. Evaluating safety data is a complex process. Standards are often lower for using safety data than for using efficacy data and so there may be more uncertainty about the results. Therefore, conclusions about safety issues are worded carefully so that information drawn from potentially flawed data regarding safety is not presented as if it is based on stronger evidence than actually exists. Safety data may be poorly collected and reported and may under-represent adverse events. There are also cautionary tales about overzealous application of weak safety evidence that may, ultimately, have caused more harms to patients than if the agent had continued to be available.

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Review Key Questions: Efficacy

Questions 1-3:

- **What is the evidence that arthroscopic lavage reduces pain and improves function?**
- **What is the evidence that arthroscopic debridement reduces pain and improves function?**
- **What is the evidence that either debridement or lavage reduces pain and improves function for any subpopulation of patients with osteoarthritis?**

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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).*

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Review Key Questions: Efficacy

Conclusion Grade: B-U

- *Only one study (Moseley 2002), could be used as the foundation for our efficacy conclusion. The authors of this RCT evaluated the confidence intervals for the Knee-Specific-Pain Score (KSPS) at two years along with other measures of pain and function and determined that they did not include a clinically meaningful difference between either the debridement group and placebo or the lavage group and placebo group.*
- *This study provides possibly useful evidence that neither arthroscopic lavage nor debridement is more effective than a placebo (sham) procedure for treatment of knee OA.*
- *Moseley (2002) study has some threats to validity, concur with AHRQ Publication and Cochrane review that it is the best available valid and clinically useful efficacy evidence upon which arthroscopy decisions should be based.*
- *The AHRQ Publication (Samson 2007) reached the following conclusion based on the Moseley study: "Osteoarthritis of the knee is a common condition. Arthroscopy with debridement and lavage is widely used in the treatment of OA of the knee, yet the best available valid and clinically useful evidence does not clearly demonstrate clinical benefit. Uncertainty regarding clinical benefit can be resolved only by rigorous, multicenter RCTs. In addition, given the public health impact of OA of the knee, research on new approaches to prevention and treatment should be given high priority."*

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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

4. What is the evidence regarding adverse events from arthroscopic debridement and lavage?

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.)

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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

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Review Key Questions: Safety

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 weak evidence.*

Review Key Questions: Cost

Key Question 5:

- ***What is the evidence regarding cost or cost-effectiveness of arthroscopic lavage or debridement?***

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

- The Osteoarthritis Research Society International (OARSI) guidelines group awarded what they consider to be a high level (level Ib grade of evidence) to many studies which were actually considered to be of low quality by the authors of the AHRQ publication.
- Grade Ib evidence is defined by the OARSI group as a single RCT; however, this is not sufficient to be considered high quality evidence — RCTs must be valid and clinically useful.
 - (See evaluation of Livesley 1991 rated grade 1b without limitations noted; AHRQ rated poor, with numerous threats to validity including lack of randomization)
- In the OARSI rating, the Moseley 2002 RCT (the only study identified as high quality by the AHRQ authors and grade B-U by our review) was not assigned an evidence grade at all by the OARSI group.

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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.

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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,

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Conclusions

- We concur with the implications stated in the AHRQ publication (Samson 2007) and the Cochrane review (Ramos 2007), namely that further high quality research is urgently needed in specific population groups. In addition, we would like to emphasize the following points:
- 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

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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>

³ The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

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 information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change 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: <http://www.gradeworkinggroup.org/FAQ/index.htm>

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

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

Safety Outcomes	Safety Evidence
Mortality	
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
Other Factors	Evidence
Durability of result	

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
Medicare	2004	No coverage for: <ul style="list-style-type: none"> • 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

Clinical Committee Evidence Votes

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 cost-effective
- 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 cost-effective 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 meeting.

- 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

Safety

- 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 life-threatening, 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?

Overall

- 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?